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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOHN MORAN, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,

Plaintiff,

v.

CLOVIS ONCOLOGY, INC., PATRICK J. MAHAFFY, and ERLE T. MAST,

Defendants.

Case No.:

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY DEMANDED

Plaintiff John Moran ("Plaintiff"), by Plaintiff's undersigned attorneys, individually and on behalf of all other persons similarly situated, alleges the following based upon personal knowledge as to Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Clovis Oncology, Inc. ("Clovis" or the "Company"), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of a class consisting of all persons and entities, other than Defendants (defined below) and their affiliates, who purchased or otherwise acquired the securities of Clovis from October 31, 2013 to November 13, 2015, inclusive (the "Class Period"), seeking to recover compensable damages caused by Defendants' violations of the federal securities laws.

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. § 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

4. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b), as Defendants conduct business in this District, has an office in this District, and a significant portion of the Defendants' actions and the subsequent damages, took place within this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the attached Certification, acquired Clovis securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

7. Defendant Clovis is a biopharmaceutical company focusing on acquiring, developing, and commercialized anti-cancer agents in the U.S. and internationally. Clovis is a Delaware corporation, headquartered in Boulder, Colorado with an office at 499 Illinois Street

Suite 230, San Francisco, California. Its common stock trades on NASDAQ under the ticker symbol "CLVS."

8. Defendant Patrick J. Mahaffy ("Mahaffy") has served as the Company's President and Chief Executive Officer ("CEO") throughout the Class Period.

9. Defendant Erle T. Mast ("Mast") has served as the Company's Chief Financial Officer ("CFO") and Executive Vice President throughout the Class Period.

10. The defendants Mahaffy and Mast are sometimes referred to herein as the "Individual Defendants."

11. Defendant Clovis and the Individual Defendants are referred to herein, collectively, as the "Defendants."

SUBSTANTIVE ALLEGATIONS

BACKGROUND

12. Clovis is a biopharmaceutical company that acquires, develops, and commercializes treatments for specific subsets of cancer. One of Clovis' most important product candidates is rociletinib, or CO-1686, which is currently in clinical development.

13. Rociletinib is a novel, oral, targeted covalent (irreversible) inhibitor of the cancer-causing mutant forms of epidermal growth factor receptor ("EGFR") currently being studied for the treatment of non-small cell lung cancer ("NSCLC"). Rociletinib was designed to selectively target both the initial activating EGFR mutations and the dominant acquired T790M resistance mutation, while sparing wild-type, or normal EGFR at anticipated therapeutic doses, with an improved toxicity profile.

14. Clovis is running the TIGER program, which is an accelerated clinical development program for rociletinib in patients with mutant EGFR non-small cell lung cancer. There are multiple ongoing clinical trials including TIGER-X, TIGER-1, TIGER-2, and TIGER-3.

15. The 2012 FDA Safety and Innovation Act created Breakthrough Therapy designation. This is intended to expedite the development and review of drugs to treat serious or life-threatening medical conditions when preliminary clinical evidence demonstrates that the drug

may have substantial improvement on at least one clinically significant endpoint over available therapies. Breakthrough Therapy designation includes all the features of the Fast Track designation, as well as more intensive guidance from the FDA on a drug's clinical development program.

MATERIALLY FALSE AND MISLEADING STATEMENTS

16. The Class Period Begins on October 31, 2013. On that day, Clovis issued a press release entitled, "Clovis Oncology Announces Third Quarter 2013 Operating Results." The press release stated in relevant part:

CLOVIS ONCOLOGY ANNOUNCES THIRD QUARTER 2013 OPERATING RESULTS

- ***CO-1686* and rucaparib *demonstrated meaningful clinical activity in data presented at recent medical meetings***
- ***67 percent objective response rate demonstrated in heavily pretreated T790M+ NSCLC patients dosed at 900mg BID free base form of CO-1686***
- **Dose escalation continues with improved hydrobromide (HBr) formulation**
- **First patient enrolled in ARIEL2 Phase II study of rucaparib in ovarian cancer**
- **Pivotal ARIEL3 study of rucaparib to commence by YE 2013**
- **Initial CO-1686 registration study to commence H1 2014**

BOULDER, Colo.--(BUSINESS WIRE)--Oct. 31, 2013-- Clovis Oncology, Inc. (NASDAQ:CLVS) today reported financial results for its third quarter ended September 30, 2013, and provided an update for its clinical development programs.

"***We are very pleased by the data recently presented for both CO-1686 and rucaparib and the progress being made on both programs,"*** said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "***Given the encouraging results we've seen for CO-1686 to date, we look forward to identifying the Phase 2 dose with our improved HBr formulation by the end of 2013, and then commencing our initial registration study in the first half of 2014. This will be our first pivotal trial of a broad and global clinical development plan for CO-1686***."

Third Quarter 2013 Financial Results

Clovis reported a net loss of $20.3 million for the third quarter of 2013, and $55.3 million for the first nine months of 2013. This compares to a net loss of $18.3

million for the third quarter and $52.9 million for the first nine months of 2012. Net loss attributable to common stockholders for the third quarter of 2013 was $0.68 per share and $2.00 per share for the year to date, compared to$0.71 per share for the third quarter and $2.15 per share for first nine months of 2012.

Research and development expenses totaled $16.1 million for the third quarter and $44.0 million for first nine months of 2013, compared to $15.5 million for the third quarter and $40.6 million for the first nine months of 2012. The increase in research and development expenses over the comparable periods in 2012 was driven by increased development activities for both CO-1686 and rucaparib, partially offset by the wind-down of development activities for CO-101 beginning in late 2012.

General and administrative expenses totaled $4.3 million for the third quarter and $11.0 million for the first nine months of 2013, compared to $2.8 million for the third quarter and $7.9 million for the first nine months of 2012. The increase in general and administrative expenses over the comparable periods in 2012 was primarily due to increased stock compensation expense for employees engaged in general and administrative functions and third party costs to support the Company's expanded activities.

Operating expenses for the third quarter of 2013 include $2.8 million of stock compensation expense, compared to $1.5 million of stock compensation expense for the third quarter of 2012. Operating expenses for the first nine months of 2013 included $6.7 million of stock compensation expense, compared to $3.6 million of stock compensation expense for the first nine months of 2012.

As of September 30, 2013, Clovis had $356.6 million in cash and cash equivalents and 30.2 million outstanding shares of common stock. The Company used $47.9 million to fund operations for the nine months ended September 20, 2013, and expects total cash burn for 2013 to be approximately $66 million.

Progress Toward 2013 Key Milestones and Objectives

The Company has made significant progress toward its clinical, regulatory and development objectives for 2013 for each of its key products; descriptions of each product and highlights of recent progress follow.

CO-1686

CO-1686 is a novel, oral, targeted, covalent inhibitor of the mutant forms of the epidermal growth factor receptor (EGFR) in development for the treatment of non-small cell lung cancer (NSCLC) and is currently in the dose-escalation portion of a Phase 1 trial. CO-1686 was designed to selectively target both the initial activating EGFR mutations as well as the T790M resistance mutation, while sparing wild-type, or "normal" EGFR at anticipated therapeutic doses.

Earlier this week, data from the ongoing CO-1686 Phase 1 dose-escalation study were presented by Professor Jean-Charles Soriaat the 15th World Conference on Lung Cancer in Sydney. Six RECIST partial responses (PR) have been observed

> to date in nine evaluable T790M positive patients dosed at 900mg BID of the free base formulation, for a 67 percent objective response rate. Eight of the nine evaluable patients, or 89 percent, experienced PRs or tumor shrinkage greater than 10 percent. These patients were heavily pretreated prior to receiving CO-1686; eight of the nine patients had progressed on an EGFR TKI (e.g. erlotinib) immediately prior to enrollment in the study. Six of the nine patients received two or more previous TKI lines. Fifty-six patients have been treated with CO-1686 to date across all dosing cohorts, with no evidence of dose-related wild-type EGFR-driven toxicities.
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> Enrollment in the ongoing Phase 1 study with the HBr formulation commenced in late August, and pharmacokinetic (PK) and safety data from this initial cohort were also presented earlier in the week in Sydney. The HBr formulation at the 500mg BID dose demonstrated substantially increased exposures over those seen with the free base formulation at 900mg BID. There has been no evidence of skin or gastrointestinal toxicity in the 500mg BID cohort, and no dose limiting toxicity. Dose escalation is ongoing with the HBr tablet formulation, currently dosing at 750mg BID, as the maximum tolerated dose (MTD) has not yet been reached.
>
> Clovis expects to establish the Phase 2 dose by year-end 2013, and to initiate the Phase 2expansion cohorts to assess efficacy in 2nd line T790M+ NSCLC patients at that time and in 1st line EGFR NSCLC patients in early 2014. The Company also expects to initiate its Phase 1 study in Japan in early 2014.
>
> In addition, based on the encouraging evidence of activity seen to date, the Company now expects to commence the initial registration study in 2nd line T790M+ NSCLC patients in the first half of 2014.
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> (Emphasis added).

17. On November 7, 2013, the Company filed a Form 10-Q for the quarter ended September 30, 2013 ("3Q 2013 10-Q") with the SEC, which provided the Company's quarterly financial results. The 3Q 2013 10-Q was signed by Defendants Mahaffy and Mast. The 3Q 2013 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Mahaffy and Mast, which stated that the financial information contained in the 3Q 2013 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting. The 3Q 2013 10-Q reaffirmed the Company's financial results previously announced on October 31, 2013.

18. On February 27, 2014, Clovis issued a press release entitled, "Clovis Oncology Announces 2013 Operating Results and Expands CO-1686 Development Program." The press release states in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES 2013 OPERATING RESULTS AND EXPANDS CO-1686 DEVELOPMENT PROGRAM
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> - *CO-1686 Phase 2 expansion cohorts increased in size to approximately 300 patients*
> - *Potential to accelerate NDA submission timeline*
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> BOULDER, Colo.--(BUSINESS WIRE)--Feb. 27, 2014-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter and year ended December 31, 2013, and provided an update on the expected milestones for its clinical development programs for 2014.
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> "2013 was obviously a great year for us and it has set the stage for what will be an even more important year for our company," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "***We are now aggressively moving forward with our plan to initiate registration studies for CO-1686 in the second quarter***. We have also initiated a global Phase 3 registration study for rucaparib and will initiate our Phase 2 lucitanib studies in the next couple of months. This has been a period of rapid progress for our company that we hope will lead to our first New Drug Application (NDA) submission in 2015.
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> "***Importantly, we have been delighted to see encouraging activity at each of the CO-1686 hydrobromide salt (HBr) doses, and we are increasing the size of our expansion cohorts to swiftly build a larger clinical data set in our T790M+ cohorts," added Mahaffy. "We are also aware that the FDA has publicly encouraged sponsors to more fully evaluate dose in their development programs prior to NDA submission. We now plan to enroll approximately 150 to 200 patients in two dose cohorts of T790M+ patients directly after progression on first and only TKI therapy, which is comparable to our TIGER2 patient population. We will also enroll approximately 150 patients in two dose cohorts of T790M+ later-line patients directly after progression on their second or later TKI therapy or subsequent chemotherapy, similar to TIGER3. We have a very active and well-tolerated drug and we are going to drive this development program rapidly and thoughtfully. Data from these studies could also serve as the basis for an earlier NDA submission."***
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> **2013 Financial Results and 2014 Financial Outlook**
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> Clovis reported a net loss of $29.2 million for the fourth quarter of 2013, and $84.5 million for the year ended December 31, 2013. This compares to a net loss of $21.1 million for the fourth quarter and $74.0 million for the year ended December 31, 2012. Net loss attributable to common stockholders for the fourth quarter of 2013 was $0.92 per share, compared to $0.81 per share for the

fourth quarter of 2012, and $2.95 per share for the year ended December 31, 2013, compared to $2.97 per share for the year ended December 31, 2012.

Research and development expenses totaled $22.5 million for the fourth quarter of 2013 and $66.5 million for full year 2013, compared to $18.3 million for the fourth quarter of 2012 and $58.9 million for the full year 2012. The increase in research and development expenses over the comparable periods in 2012 was driven by increased development activities for both CO-1686 and rucaparib, partially offset by the wind-down of development activities for CO-101 beginning in late 2012. As expected, research and development expenses for the fourth quarter of 2013 increased over the third quarter of 2013 by $6.5 million due primarily to the initiation of the ARIEL2 and ARIEL3 rucaparib clinical studies and the manufacturing of clinical supplies for both the rucaparib and CO-1686 programs.

General and administrative expenses totaled $5.5 million for the fourth quarter of 2013 and $16.6 million for the full year 2013, compared to $2.8 million for the fourth quarter of 2012 and $10.6 million for the full year 2012. The increase in general and administrative expenses over the comparable periods in 2012 was primarily due to increased stock compensation expense for employees engaged in general and administrative functions and third party costs to support the Company's expanded activities. In addition, general and administrative expenses for 2013 were impacted by transaction costs related to the Company's acquisition of EOS (Ethical Oncology Science) S.p.A., which totaled $1.6 million for the fourth quarter of 2013 and $2.2 million for the full year 2013.

Operating expenses for the fourth quarter of 2013 include $2.8 million of stock compensation expense, compared to $1.3 million of stock compensation expense for the fourth quarter of 2012. Operating expenses for the full year 2013 included $9.5 million of stock compensation expense, compared to $4.9 million of stock compensation expense for the comparable period in 2012.

As of December 31, 2013, Clovis had $323.2 million in cash and cash equivalents and 33.9 million outstanding shares of common stock. The Company used $71.7 million to fund operations for the year ended December 31, 2013, and expects a cash burn of approximately $120 million for 2014.

Progress Toward 2014 Key Milestones and Objectives

The Company has substantive clinical, regulatory and development objectives for 2014 for each of its key products; descriptions of each product, highlights of recent progress and planned objectives follow.

CO-1686

CO-1686 is a novel, oral, targeted, covalent inhibitor of the mutant forms of the epidermal growth factor receptor (EGFR) in development for the treatment of non-small cell lung cancer (NSCLC). CO-1686 was designed to selectively target both the initial activating EGFR mutations as well as the T790M resistance mutation, while sparing wild-type, or "normal" EGFR.

> The Company has seen no evidence of TKI-related EGFR wild-type rash and diarrhea at any dose or formulation studied. The dose-limiting toxicity of hyperglycemia is easily managed and most patients are asymptomatic. CO-1686 is the only EGFR-directed therapy to spare wild-type EGFR in clinical studies, which the Company believes represents a significant point of differentiation from approved EGFR inhibitors and those currently in development.
>
> The Company is currently enrolling two Phase 2 expansion cohorts of its Phase 1/2 study in EGFR mutant patients with the T790M mutation; the first includes approximately 150 to 200 T790M+ patients directly after progression on their first and only TKI therapy, comparable to the population we will seek to enroll in our TIGER2 registration study. The second cohort includes approximately 150 later-line T790M-positive patients directly after progression on their second or later TKI therapy or subsequent chemotherapy, similar to the population we seek to enroll in TIGER3.
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> Clovis expects to initiate three registration studies in the TIGER (Third-generation Inhibitor of Mutant EGFR in Lung Cancer) program during the first half of 2014. The TIGER2 study, in T790M+ patients directly after progression on their first and only TKI therapy, and the TIGER3 study, in later-line patients directly after progression on their second or later TKI therapy or subsequent chemotherapy, are planned to initiate by the end of Q2 2014. The Phase 2 portion of the TIGER1 study, which is a randomized Phase 2/3 registration study of CO-1686 vs. erlotinib in newly-diagnosed EGFR mutant patients who have not had TKI therapy but who may have received one type of chemotherapy, will begin in the second quarter of 2014 as well. The Company also expects to initiate its Phase 1 study in Japan during the first quarter of 2014.
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> An update of clinical results from the Phase 1 study, including the first presentation of results from patients treated with the hydrobromide (HBr) salt formulation that will be used in all clinical studies going forward, will be presented in a Proffered Paper (Oral) presentation during the 4th European Lung Cancer Conference (ELCC) in Geneva. These data will be presented by Heather Wakelee, MD, Associate Professor of Medicine, Oncology at Stanford University, and an investigator on the study, on March 27during the session titled "Advanced Disease with Targeted Agents" from 9:00-10:30am CET.
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> (Emphasis added).

19. On February 28, 2014, the Company filed its annual report on Form 10-K for the year ending December 31, 2013 (the "2013 10-K"). The 2013 10-K was signed by Defendants Mahaffy and Mast. The 2013 10-K contained signed certifications pursuant SOX by Defendants Mahaffy and Mast. The 2013 10-K reaffirmed Clovis' financial results previously announced on February 27, 2014.

20. On May 8, 2014, Clovis issued a press release entitled, "Clovis Oncology Announces First Quarter 2014 Operating Results." The press release stated in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES FIRST QUARTER 2014 OPERATING RESULTS
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> - *Encouraging CO-1686 clinical activity and progression-free survival (PFS) in non-small cell lung cancer (NSCLC) reported atEuropean Lung Cancer Conference in late March;*
> - *CO-1686 Phase 2 expansion cohorts enrolling*
> - *TIGER1 and TIGER2 studies to initiate shortly*
> - *CO-1686 New Drug Application (NDA) submission planned by mid-2015*
> - *Clovis to present updated data on its pipeline products at ASCO May 30-June 3*
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> BOULDER, Colo.--(BUSINESS WIRE)--May 8, 2014-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its first quarter ended March 31, 2014, and provided an update on the Company's clinical development programs for the rest of 2014.
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> "This is an exciting time for our clinical development programs and I am proud of what our team has accomplished to date," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "During the next few months, we are initiating two of our Phase 2 global TIGER studies for CO-1686 in EGFR-driven NSCLC, the Phase 2 study of rucaparib in pancreatic cancer patients with BRCA mutations, as well as Phase 2 studies of lucitanib in both breast cancer and squamous NSCLC. We look forward to providing updates for each of our products in development at ASCO later this month, and continuing to advance our clinical programs into later-stage development, most importantly, with the intention to utilize the CO-1686 Phase 2 expansion cohorts and TIGER2 as the basis for an NDA submission to the FDA by mid-2015."
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> **Q1 2014 Financial Results and Financial Outlook**
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> Clovis reported a net loss for the first quarter of 2014 of $30.7 million, or $0.91 per share. Net cash burn for the first quarter of 2014 was $19.6 million. The Company's net loss was impacted by a number of infrequently occurring transactions, including the following:
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> - Milestone revenue of $13.6 million pursuant to our collaboration and license agreement for lucitanib with Les Laboratoires Servier (Servier), earned as a result of the expiration of the opposition period of a lucitanib European patent.
> - Acquired in-process research and development expense totaling $8.4 million associated with milestone payments incurred for CO-1686 ($5.0 million for the initiation of a Phase 2 clinical study) and lucitanib ($3.4

million as a pass-through of a portion of the patent milestone received from Servier).

- $3.4 million of amortization expense of an intangible asset that was established as part of the purchase accounting for the acquisition of EOS S.p.A. (EOS) in the fourth quarter of 2013. This amortization expense was also triggered by the receipt of the milestone payment from Servier.
- Income tax expense of $2.1 million, due primarily to projected 2014 taxable income earned in Italy as a result of the receipt of the Servier milestone payment.

The Company's net loss for the first quarter of 2013 totaled $15.7 million, or $0.60 per share. The increase in the loss for the first quarter of 2014 is due primarily to expanded development activities for the CO-1686 and rucaparib programs as Clovis initiated additional clinical studies in both programs.

Research and development expenses totaled $24.2 million for the first quarter of 2014, compared to $12.1 million for the first quarter of 2013. The increase in expense is due to the initiation of the ARIEL2 and ARIEL3 studies for rucaparib, an increase in the number of patients enrolled in the Phase 1/2 study for CO-1686, the initiation of the TIGER2 and the Japanese Phase 1 studies for CO-1686, and increased manufacturing of clinical drug supplies for the CO-1686 and rucaparib programs.

General and administrative expenses totaled $5.3 million for the first quarter of 2014, compared to $3.2 million for the first quarter of 2013. This increase is largely due to higher share-based compensation expense for employees engaged in general and administrative activities.

Operating expenses for the first quarter of 2014 totaled $42.1 million, inclusive of the acquired in-process research and development and amortization expenses described above. Total operating expenses include non-cash charges totaling $9.2 million for share-based compensation expense, amortization of an intangible asset, and the accretion of contingent purchase consideration associated with the EOS acquisition.

As of March 31, Clovis had $303.7 million in cash and cash equivalents and 33.9 million outstanding shares of common stock. The Company continues to expect cash burn for 2014 will total approximately $120 million and to end the year with approximately $200 million in cash.

Progress Toward 2014 Key Milestones and Objectives

The Company has substantive clinical, regulatory and development objectives for 2014 for each of its products; highlights of recent progress and planned objectives follow.

CO-1686

An update of clinical results from the CO-1686 Phase 1 study were presented in a

Proffered Paper (Oral) presentation during the 4th European Lung Cancer Conference (ELCC) in Geneva in late March by Heather Wakelee, MD, Associate Professor of Medicine, Oncology at Stanford University, and an investigator participating in the study. Highlights of the data presented include the following:

- Evidence of activity: Fourteen RECIST partial responses (PRs) were achieved in 22 evaluable T790M positive patients, for an objective response rate of 64 percent; ten of those responders started CO-1686 therapy immediately following progression on a prior TKI. Twenty of the 22 evaluable T790M positive patients, or 91 percent, have experienced stable disease or a PR. While median duration of response cannot yet be estimated in the T790M positive patients, PFS greater than six months in the evaluable, heavily-pretreated T790 positive patient population has been observed with the median not yet reached. Median PFS in T790M negative patients was approximately three months.
- Safety: CO-1686 is well-tolerated, with only one patient who discontinued treatment with CO-1686 due to adverse events. The Company has seen no evidence of TKI-related EGFR wild-type rash and diarrhea at any dose or formulation studied. The most common adverse events were hyperglycemia, nausea, diarrhea, decreased appetite and vomiting, and these were mostly grade 1 in severity. The most common grade 3 adverse event was hyperglycemia, which was observed in 19 percent of patients. This is readily managed with a commonly-prescribed single oral agent. Grade 3 QTc prolongation was observed in five percent of patients and was asymptomatic.

The next update of CO-1686 clinical data will be presented at the 2014 American Society of Clinical Oncology Annual Meeting in a Clinical Science Symposium on lung cancer taking place on Saturday, May 31.

CO-1686 is the only EGFR-directed therapy to spare wild-type EGFR in clinical studies, which the Company believes represents a significant point of differentiation from approved EGFR inhibitors and those currently in clinical development.

The Company is currently enrolling two Phase 2 expansion cohorts of its Phase 1/2 study in EGFR mutant patients with the T790M mutation; the first includes approximately 150 to 200 T790M positive patients directly after progression on their first and only TKI therapy, comparable to the population we will seek to enroll in our TIGER2 registration study. The second cohort includes approximately 150 to 200 later-line T790M positive patients after progression on their second or later TKI therapy or subsequent chemotherapy. Both cohorts are exploring doses of 500mg, 625mg and 750mg BID. Given the meaningful efficacy now observed at each of these doses, Clovis no longer intends to pursue a dose of 1000mg BID as there is no evident increase in efficacy to offset the

increased and dose-related toxicities.

Data from the expansion cohorts, combined with data from TIGER2, are expected to serve as the basis of an NDA submission for CO-1686 by mid-2015.

Clovis expects to initiate three registration studies in the TIGER program during 2014. The TIGER2 study, in T790M positive patients directly after progression on their first and only TKI therapy, is expected to begin enrolling patients at a dose of 625mg BID during the second quarter. The Phase 2 portion of the TIGER1 study, which is a randomized Phase 2/3 registration study of CO-1686 vs. erlotinib in newly-diagnosed EGFR mutant patients is expected to begin in mid-2014, and the TIGER3 study, a randomized, comparative study versus chemotherapy in T790M positive patients directly after progression on their first and only TKI therapy, is expected to initiate during the second half of 2014.

The Company initiated its Phase 1 study of CO-1686 in Japan during the first quarter of 2014.

21. On May 9, 2014, the Company filed a Form 10-Q for the quarter ended March 31, 2014 ("1Q 2014 10-Q") with the SEC, which provided the Company's quarterly financial results. The 1Q 2014 10-Q was signed by Defendants Mahaffy and Mast. The 1Q 2014 10-Q contained signed certifications pursuant SOX by Defendants Mahaffy and Mast, which stated that the financial information contained in the 1Q 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting. The 1Q 2014 10-Q reaffirmed the Company's financial results previously announced on May 8, 2014.

22. On May 19, 2014, the Company issued a press release, "Clovis Oncology Receives Breakthrough Therapy Designation for CO-1686 For the Treatment of Second-Line EGFR Mutant Non-Small Cell Lung Cancer (NSCLC) in Patients With the T790M Mutation." The press release announced in relevant part:

CLOVIS ONCOLOGY RECEIVES BREAKTHROUGH THERAPY DESIGNATION FOR CO-1686 FOR THE TREATMENT OF SECOND-LINE EGFR MUTANT NON-SMALL CELL LUNG CANCER (NSCLC) IN PATIENTS WITH THE T790M MUTATION

BOULDER, Colo.--(BUSINESS WIRE)--May 19, 2014-- Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for the Company's investigational agent CO-1686 as monotherapy for the treatment of second-line EGFR mutant NSCLC in patients with the T790M mutation. The Breakthrough Therapy designation was granted based on interim efficacy and safety results from an ongoing Phase 1/2 study of CO-1686. CO-1686 is the Company's novel, oral, targeted covalent (irreversible) inhibitor of mutant forms of the epidermal growth factor receptor (EGFR) for the treatment of non-small

cell lung cancer in patients with initial activating EGFR mutations as well as the dominant resistance mutation T790M.

"We very much appreciate this designation by FDA, which recognizes the meaningful benefit CO-1686 may provide patients with T790M positive NSCLC," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "This designation is well timed for us as well, as the increased interaction with FDA that it provides will come as we are initiating our registration studies and preparing to submit our initial New Drug Application (NDA) by mid-2015."

Interim results from an ongoing Phase 1/2 study of CO-1686 were presented at the 4th European Lung Cancer Conference (ELCC) in Geneva in late March. An objective response rate of 64 percent in 14 of 22 evaluable T790M positive patients was observed. CO-1686 is well-tolerated, with only one patient who discontinued treatment with CO-1686 due to adverse events. There was no evidence of systemic wild-type EGFR inhibition.

The next update of CO-1686 clinical data will be presented at the 2014 American Society of Clinical Oncology Annual Meeting in a Clinical Science Symposium titled, "Targeting EGFR: The Next 10 Years", taking place on Saturday, May 31 in Chicago.

The Company is currently enrolling two Phase 2 expansion cohorts of its Phase 1/2 study in EGFR mutant patients with the T790M mutation. Data from the expansion cohorts, combined with data from the TIGER2 study, in T790M positive patients directly after progression on their first and only TKI therapy, are expected to serve as the basis of an NDA submission for CO-1686 by mid-2015.

23. On May 31, 2014, data from the clinical trials of rociletinib was presented at the 2014 American Society of Clinical Oncology ("ASCO") annual meeting in Chicago. The presentation was entitled, "First-in-human evaluation of CO-1686, an irreversible, highly selective tyrosine kinase inhibitor of mutations of EGFR (activating and T790m)."

24. On May 31, 2014, the Company issued a press release entitled, "Clovis Oncology's CO-1686 Demonstrates Compelling Clinical Activity and Progression-Free Survival (PFS) in Updated Phase 1/2 Study Results in Patients With EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)." The press release discussed the data that was presented at ASCO, stating in relevant part:

CLOVIS ONCOLOGY'S CO-1686 DEMONSTRATES COMPELLING CLINICAL ACTIVITY AND PROGRESSION-FREE SURVIVAL (PFS) IN UPDATED PHASE 1/2 STUDY RESULTS IN PATIENTS WITH EGFR-MUTANT NON-SMALL CELL LUNG CANCER (NSCLC)

- **58% objective response rate observed to date in 40 evaluable heavily-pretreated T790M+ patients in Phase 1 and early Phase 2 expansion cohorts**

- **Current estimate of median PFS greater than 12 months in T790M+ patient population; observed median not yet reached**
- **Well-tolerated – majority of treatment-related adverse events are grade 1-2 and manageable**
- **Only TKI to completely spare wild-type EGFR signaling**
- **Breakthrough Therapy designation granted by FDA earlier this month**
- **New Drug Application (NDA) submission planned by mid-2015**

CHICAGO-- (BUSINESS WIRE)-- May 31, 2014 -- ***Clovis Oncology (NASDAQ:CLVS) announced today updated findings from the Phase 1 and early Phase 2 portions of its ongoing Phase 1/2 clinical study of CO-1686, the Company's novel, oral, targeted covalent (irreversible) inhibitor of mutant forms of the epidermal growth factor receptor (EGFR) for the treatment of non-small cell lung cancer in patients with initial activating EGFR mutations as well as the dominant resistance mutation T790M***. These data are being presented today in an oral presentation by Dr. Lecia Sequist at the 2014 American Society of Clinical Oncology (ASCO) annual meeting in Chicago.

"Currently, there are no approved treatments for EGFR patients with acquired resistance to targeted therapy," said Lecia V. Sequist, MD, MPH, Massachusetts General Hospital Cancer Center and Associate Professor of Medicine at Harvard Medical School and the lead investigator for the Phase 1/2 study of CO-1686. "This ever-growing population of patients is in dire need of effective agents. The initial experience with CO-1686 provides hope that we are finally entering an era where we may be able to successfully target resistance to EGFR inhibitors."

"In the year since our first presentation of clinical data for CO-1686, we have made great strides in the development of this drug," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are extremely pleased with the consistency of the efficacy demonstrated to date, the growing evidence of a lengthy duration of benefit and that CO-1686 is so well-tolerated with a manageable side effect profile. Additionally, the receipt of Breakthrough Therapy Designation from FDA earlier this month supports our commitment to file an NDA by mid-2015 and make this drug available to treating physicians and the patients that may benefit as rapidly as possible."

The Phase 1 dose escalation portion of the study is being conducted in the United States, France and Australia in patients with metastatic or unresectable recurrent NSCLC and a documented EGFR mutation. Patients were not required to be T790M positive for the Phase 1 portion of the study but had to have progressed on prior EGFR-directed tyrosine kinase inhibitor (TKI) therapy (prior chemotherapy was also allowed).

The two Phase 2 expansion cohorts are currently enrolling in the United States, Europe, and Australia in EGFR mutant patients with the T790M mutation. The first cohort includes approximately 150 to 200 T790M positive patients directly after progression on their first and only TKI therapy, comparable to the population planned for the TIGER2 registration study. The second cohort includes approximately 150 to 200 later-line T790M positive patients after progression on their second or later TKI therapy or subsequent chemotherapy. ***Both cohorts are***

exploring doses of 500mg, 625mg and 750mg BID.

Approximately 160 patients have been treated with CO-1686 to date across all dosing cohorts in the trial. Data from 81 evaluable patients treated with CO-1686 at efficacious doses (comprising patients treated with 900mg BID of freebase or any dose of the hydrobromide salt (HBr) formulation) were presented today, including 72 from the Phase 1 study and nine from the early part of the Phase 2 portion of the study. Of these 81 patients, 40 are centrally-confirmed T790M positive.

Patients enrolled in the Phase 1 study were heavily pretreated prior to receiving CO-1686; 75 percent of patients across all doses had immediately progressed on TKI therapy prior to CO-1686 treatment. The median number of previous lines of therapy across patients at all doses was three; the median number of previous TKI lines was two.

Evidence of Activity

In the 40 evaluable centrally-confirmed T790M positive patients across efficacious dose levels in the Phase 1 dose-expansion study and the early Phase 2 expansion cohorts, 23 partial responses (PRs) have been observed to date, for a 58 percent objective response rate (ORR). Thirty-six of the 40 evaluable T790M positive patients, or 90 percent, have experienced stable disease or a PR. Central nervous system (CNS) responses have also been observed in heavily pre-treated T790M positive patients.

The median duration of response cannot yet be determined in the T790M positive patients. Similarly, median PFS has not been reached. However, follow-up for some patients exceeds one year, and the current estimate for median PFS is greater than 12 months.

Safety and Tolerability

CO-1686 is well-tolerated, with no evidence of systemic wild-type EGFR inhibition. In the Phase 1 study, the most common adverse events were nausea, hyperglycemia, diarrhea, vomiting and decreased appetite, and these were mostly grade 1 or 2 in severity. The most common grade 3 adverse event was hyperglycemia, which was observed in 22 percent of patients. Hyperglycemia, when observed and requiring treatment, is typically managed with a commonly-prescribed single oral agent.

Presentation Details

The presentation, titled “First-in-human evaluation of CO-1686: An irreversible, highly-selective tyrosine kinase inhibitor of mutations of EGFR (activating and T790M)” was presented on Saturday, May 31, during the Clinical Science Symposium session titled “Targeting EGFR: The Next 10 Years”, from 8:00 to 9:30am Central Time. The presentation is available atwww.clovisoncology.com.

CO-1686 Clinical Development

The Company is currently enrolling two Phase 2 expansion cohorts of its Phase 1/2 study in EGFR mutant patients with the T790M mutation; the first includes approximately 150 to 200 T790M positive patients directly after progression on

> their first and only TKI therapy, comparable to the population the Company will seek to enroll in its TIGER2 registration study. The second cohort includes approximately 150 to 200 later-line T790M positive patients after progression on their second or later TKI therapy or subsequent chemotherapy. ***Both cohorts are exploring doses of 500mg, 625mg*** and 750mg BID.
>
> ***Data from the expansion cohorts, combined with data from TIGER2, are expected to serve as the basis of an NDA submission for CO-1686 by mid-2015.***
>
> Clovis expects to initiate three registration studies in the TIGER program during 2014. The TIGER2 study, in T790M positive patients directly after progression on their first and only TKI therapy, is expected to begin enrolling patients at a dose of 625mg BID during the second quarter. The Phase 2 portion of the TIGER1 study, which is a randomized Phase 2/3 registration study of CO-1686 vs. erlotinib in newly-diagnosed EGFR mutant patients is expected to begin in mid-2014, and the TIGER3 study, a randomized, comparative study versus chemotherapy in T790M positive patients directly after progression on their first and only TKI therapy, is expected to initiate during the second half of 2014.
>
> The Company initiated its Phase 1 study of CO-1686 in Japan during the first quarter of 2014.
>
> (Emphasis added).

25. On June, 23, 2014, the Company issued a press release entitled, "Clovis Oncology Announces First Patient Enrolled in Tiger2 Study." The press release further detailed the data that was presented at the 2014 ASCO annual meeting on May 31, 2014, stating in relevant part:

> ***Data recently presented at the 2014 American Society of Clinical Oncology annual meeting included activity and safety results in 40 evaluable centrally-confirmed T790M positive patients across efficacious dose levels in the Phase 1 dose-expansion study and the early Phase 2 expansion cohorts***. These include 23 partial responses (PRs) observed as of early May, for a 58 percent objective response rate (ORR). Thirty-six of the 40 evaluable T790M positive patients, or 90 percent, have experienced stable disease or a PR. Central nervous system (CNS) responses have also been observed in heavily pre-treated T790M positive patients. The median duration of response cannot yet be determined in the T790M positive patients. Similarly, median PFS has not been reached. However, follow-up for some patients exceeds one year, and the current estimate for median PFS is greater than 12 months. CO-1686 is well-tolerated, with no evidence of systemic wild-type EGFR inhibition. In the Phase 1 study, the most common adverse events were nausea, hyperglycemia, diarrhea, vomiting and decreased appetite, and these were mostly grade 1 or 2 in severity. The most common grade 3 adverse event was hyperglycemia, which was observed in 22 percent of patients. Hyperglycemia, when observed and requiring treatment, is typically managed with a commonly-prescribed single oral agent.

> Breakthrough therapy designation was granted by the FDA last month for CO-1686 as monotherapy for the treatment of mutant EGFR NSCLC in patients with the T790M mutation after progression on EGFR-directed therapy.

(Emphasis added).

26. On August 7, 2014, the Company issued a press release entitled, "Clovis Oncology Announced Second Quarter 2014 Operating Rsults." The press release stated in part:

> CLOVIS ONCOLOGY ANNOUNCES SECOND QUARTER 2014 OPERATING RESULTS
>
> *CO-1686 NDA submission expected by mid-2015*
>
> *CO-1686 Breakthrough Therapy designation granted during Q2*
>
> *Proposed INN rociletinib assigned to CO-1686*
>
> *Rociletinib and rucaparib data updates to be presented at medical conferences in Fall 2014*
>
> BOULDER, Colo.--(BUSINESS WIRE)--Aug. 7, 2014-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its second quarter ended June 30, 2014, and provided an update on the Company's clinical development programs for the rest of 2014.
>
> "This is a very busy and exciting time at our Company," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are rapidly enrolling patients in the rociletinib (CO-1686) Phase 2 expansion cohorts and TIGER2 studies, preparing for our NDA submission in mid-2015 and beginning to build out our commercial and medical affairs leadership in anticipation of a potential launch by year-end 2015. Additionally, the emerging results from the rucaparib ARIEL2 study are extremely encouraging and we look forward to presenting data for each of these programs at scientific meetings in the fall."
>
> * * *
>
> **Progress Toward 2014 Key Milestones and Objectives**
>
> The Company has substantive clinical, regulatory and development objectives for 2014 for each of its products; highlights of recent progress and planned objectives follow.
>
> Rociletinib
>
> An update of clinical data from the rociletinib Phase 1/2 study were presented in early June in an oral session at the American Society of Clinical Oncology (ASCO) Annual Meeting. ***Highlights from the data presented for evaluable, centrally-confirmed T790M positive patients treated at a therapeutic dose of rociletinib included a 58 percent objective response rate, and a 90 percent disease control rate.*** The median duration of response could not yet be determined, and similarly, median progression-free survival (PFS) had not yet been reached. However, follow-up for some patients exceeded one year and the estimate for median PFS was greater than 12 months. Rociletinib is well-

> tolerated, with no evidence of wild-type EGFR inhibition. The most common adverse events were nausea, hyperglycemia, diarrhea, vomiting and decreased appetite, and these were mostly grade 1 or 2 in severity.
>
> Rociletinib is the only EGFR-directed therapy to spare wild-type EGFR in clinical studies, which the Company believes represents a significant point of differentiation from approved EGFR inhibitors and those currently in clinical development.
>
> The next update of CO-1686 clinical data is expected to take place at the 26th EORTC-AACR-NCI Symposium on Molecular Targets and Cancer Therapeutics in Barcelona in mid-November.
>
> The Company is currently enrolling two Phase 2 expansion cohorts of its Phase 1/2 study in EGFR mutant patients with the T790M mutation; the first includes approximately 150 to 200 T790M positive patients directly after progression on their first and only TKI therapy, comparable to the TIGER2 registration study patient population. The second cohort includes approximately 150 to 200 later-line T790M positive patients after progression on their second or later TKI therapy or subsequent chemotherapy. Both cohorts are exploring doses of 500mg, 625mg and 750mg BID. The TIGER2 study, in T790M positive patients directly after progression on their first and only TKI therapy, began enrolling patients earlier in the second quarter at a dose of 625mg BID.
>
> Data from the expansion cohorts, combined with data from TIGER2, are expected to serve as the basis of an NDA submission for rociletinib by mid-2015.
>
> In May, the U.S. FDA granted Breakthrough Therapy designation for rociletinib as treatment for mutant NSCLC in patients with the T790M mutation after progression on EGFR-directed therapy.
>
> Clovis expects to initiate two more studies in the TIGER program during 2014. The TIGER1 study, a randomized Phase 2/3 registration study of rociletinib versus erlotinib in newly-diagnosed EGFR mutant patients is expected to begin shortly. The TIGER3 study, a randomized, comparative study of rociletinib versus chemotherapy in patients with EGFR-mutant NSCLC and acquired TKI resistance, is expected to begin during the second half of 2014. In addition, the Company initiated its Phase 1 study of rociletinib in Japan earlier this year.
>
> (Emphasis added).

27. On August 7, 2014, the Company held a conference call to discuss the second quarter of 2014 earnings. On the conference call, Defendant Mahaffy stated in relevant part:

> We made significant progress during the second quarter. I like to improve the receipt of breakthrough designation for CO-1686 in May. Data updates at ASCO in late May or June and continue to advance our clinical development programs with the initiation of multiple clinical studies during the quarter.
>
> Importantly, these include the initiation of the TIGER2 study or 1686, which together with the Phase 2 expansion in cohort performed the basis of our NDA

submission plan from mid-2015. Let me start with 1686, which was recently assigned as proposed international non-proprietary name or INM. Lucitanib we try will attempt to you going forward as we plan to assemble several times between the two things during this call. At ASCO we announced the most update of rociletinib clinical data which continues to demonstrate that rociletinib is a very active and well tolerated drug. Highlights of the data presented at ASCO include the following.

58% objective response rate was achieved in evaluable, centrally-confirmed T790M positive patients treated with the therapeutic dose, and a 90% of that patient population achieved disease control defined by the disease stabilization or an objective response. The median duration of response could not yet be determined in the T790M positive patients and similarly, median progression-free survival or PFS had not been reached. However, follow-up for some patients now exceeds one year.

These data continue to mature and we remain extremely encouraged by the impressive durability and benefit we are seeing, potentially longer than the median PFS observed in newly diagnosed patients treated with front-line TKI such as erlotinib and this reinforces our belief that inhibition of EGFR bio metabolite maybe contributing to this.

28. Further on the conference call, Andrew Allen, Clovis' EVP of Clinical and Pre-Clinical Develioment and CMO had the following exchange with Brian Klein, an analyst at Stifel, stating in relevant part:

Brian Klein - Stifel
Great thanks. It's Brian Klein. First question on the selection of the 625 milligram dose for TIGER1 and TIGER3, can you walk us through what criteria you used to make that dose selection please?

Patrick Mahaffy - President and CEO

Andrew?

Andrew Allen - EVP of Clinical and Pre-Clinical Development and CMO
Sure. It was mostly clinical data that has influenced that decision. The initial Phase 1 study like most Phase 1 studies is in relatively small numbers of patients. And it's very hard with well tolerated drugs to really kind of get a strong sense of where the optimum doze exactly sits. And so, treating more patients at the various doses is the only way you can truly choose between doses? ***And so we've been relying mostly on clinical data to inform that selection of the optimum dose. And obviously what we're trading off is efficacy on a one hand and toxicity on the other hand and trying to find the sweet spot where we retain all efficacy but we minimize toxicity. And that approach led us to 625 milligrams BID.***

Brian Klein - Stifel

> Great. In terms of those two studies, is there an opportunity to either dose escalate or dose intensify if the patient isn't responding after a certain amount of time.
>
> **Andrew Allen** - EVP of Clinical and Pre-Clinical Development and CMO
> It depends on the phase of study. Obviously the later of the phase, the more flexibility you offer physicians early on when one is more cautious because you have less drug experience, you do not allow such flexibility. But in latest studies we typically do permit escalation if deemed appropriate. Obviously we've cleared doses all the way up to a 1,000 milligrams BID is being safe for the Phase 1 study and therefore we have cover for dose escalation from 625 if it's regarded as appropriate.
>
> **Brian Klein** - Stifel
>
> Great, Thanks.
>
> **Andrew Allen** - EVP of Clinical and Pre-Clinical Development and CMO
> Brian, one thing, Brian I can chip into, ***one thing to remind you is we have basically equivalent efficacy across all of these efficacious doses including 900 mgs of the freebase, 500 mgs BID, 625 and 750.*** So, I don't think at 625 we're treating of efficacy, it's a very active drug and contributed 90% to diseases control rate that we reported ASCO and before.

(Emphasis added).

29. On August 8, 2014, the Company filed a Form 10-Q for the quarter ended June 30, 2014 ("2Q 2014 10-Q") with the SEC, which provided the Company's quarterly financial results. The 2Q 2014 10-Q was signed by Defendants Mahaffy and Mast. The 2Q 2014 10-Q contained signed certifications pursuant SOX by Defendants Mahaffy and Mast, which stated that the financial information contained in the 2Q 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

30. The 2Q 2014 10-Q discussed rociletinib, stating in relevant part:

> The Company received notice on July 30, 2014 that the nonproprietary name *rociletinib* was adopted for our drug candidate CO-1686 by the United States Adopted Names Council. All future references to this drug candidate will now be presented as rociletinib.
>
> **Product License Agreements**
>
> ***Rociletinib (CO-1686)***
>
> In May 2010, we entered into a worldwide license agreement with Avila (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. Rociletinib was identified as the lead inhibitor candidate under the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and

commercialize rociletinib. We made an up-front payment of $2.0 million upon execution of the license agreement, a $4.0 million milestone payment in the first quarter of 2012 upon the acceptance by the U.S. Food and Drug Administration, or FDA, of our investigational new drug, or IND, application for rociletinib, and a $5.0 million milestone payment in the first quarter of 2014 upon the initiation of the Phase II study for rociletinib. We recognized all payments as acquired in-process research and development expense. We are obligated to pay royalties on net sales of rociletinib, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of our development expenses. This option must be exercised within a limited period of time after Celgene is notified by us of our intent to pursue regulatory approval of rociletinib in the United States or the European Union as a first-line treatment. Such notice was provided to Celgene on June 4, 2014. We may be required to pay up to an additional aggregate of $110.0 million in additional development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, we may be required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. ("Gatekeeper") to acquire exclusive rights under patent applications associated with mutant EGFR inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an up-front payment of $250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. If rociletinib is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

31. On November 6, 2014, the Company issued a press released entitled, "Clovis Oncology Announces Third Quarter 2014 Operating Results." The press release stated in relevant part:

CLOVIS ONCOLOGY ANNOUNCES THIRD QUARTER 2014 OPERATING RESULTS

Data updates for rucaparib and rociletinib to be presented in oral presentations at the ENA Symposium November 20 and 21

$278.3 million raised in September sale of senior convertible notes

Encouraging rucaparib data in ovarian cancer presented at ESMO

First patients enrolled in lucitanib Phase 2 studies in breast cancer and squamous NSCLC

Rociletinib (CO-1686) NDA and MAA submissions expected in mid-2015

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 6, 2014-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its third quarter ended September 30, 2014, and provided an update on the Company's clinical development

programs for the rest of 2014.

"We look forward to presenting interim data later this month at ENA 2014 from the Phase 2 TIGER-X study of rociletinib in EGFR-driven non-small cell lung cancer, and the first clinical outcomes data, including in the pre-specified BRCA-ness population, from the prospective ARIEL2 treatment study of rucaparib in ovarian cancer," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "In addition, we remain on track to submit our NDA for rociletinib in mid-2015, and we continue to prepare for and build out our commercial and medical affairs leadership teams in anticipation of a potential U.S. launch by year-end 2015."

Q3 2014 Financial Results and Financial Outlook

Clovis reported a net loss for the third quarter of 2014 of $39.6 million ($1.17 per share), and $105.1 million ($3.10 per share) for the first nine months of 2014, compared to net losses of $20.3 million ($0.68 per share) and $55.3 million ($2.00 per share) for the comparable periods of 2013, respectively.

Research and development expenses totaled $35.0 million for the third quarter of 2014 and $87.6 million for the first nine months of 2014, compared to $16.1 million for the third quarter and $44.0 million for the first nine months of 2013. The increase in expenses for both the three and nine month periods is due primarily to the initiation of the ARIEL2 and ARIEL3 studies for rucaparib, an increase in the number of patients enrolled in the Phase 1/2 study for rociletinib, the initiation of the TIGER-2 and the Japanese Phase 1 studies for rociletinib, increased manufacturing of clinical drug supplies for the rociletinib and rucaparib programs, and increased personnel-related expenses associated with the hiring of additional staff to support the Company's expanded development activities.

General and administrative expenses totaled $5.3 million for the third quarter of 2014 and $15.9 million for the first nine months of 2014, compared to $4.3 million for the third quarter and $11.0 million for the first nine months of 2013. The increase for both periods is primarily due to higher share-based compensation expense for employees engaged in general and administrative activities.

In the first quarter of 2014, the Company recorded milestone revenue of $13.6 million received pursuant to our collaboration and license agreement for lucitanib and also recognized charges for acquired in-process research and development expense totaling$8.4 million associated with milestone payments incurred for rociletinib and lucitanib. An additional charge for acquired in-process research and development expense of $0.4 million was recorded in the second quarter of 2014 related to the achievement of a Phase 2 milestone for rucaparib.

Operating expenses for the third quarter of 2014 totaled $41.1 million, and $118.2 million for the first nine months of 2014, inclusive of the acquired in-process research and development expense described above. Total operating expenses include non-cash charges totaling $6.3 million for the third quarter and $21.5 million for the first nine months of 2014 for share-based compensation expense and amortization of an intangible asset and the accretion of contingent purchase consideration associated with the 2013 acquisition of Ethical Oncology Science, S.p.A.

Net cash burn for the third quarter of 2014 totaled $35.0 million, and $85.0 million for the first nine months of 2014. As ofSeptember 30, Clovis had $516.6 million in cash and cash equivalents and 34.0 million outstanding shares of common stock. InSeptember 2014, the Company raised net proceeds of $278.3 million through its sale of 2.5% convertible senior notes. The Company continues to expect operating cash burn for 2014 will total approximately $120 million and to end the year with approximately $480 million in cash.

Progress Toward 2014 Key Milestones and Objectives

Highlights of recent progress and planned objectives for each product follows:

Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the primary resistance mutation, T790M, which develops in 60 percent of patients treated with first- and second-generation EGFR inhibitors.

As reported at ASCO earlier this year, rociletinib has demonstrated compelling efficacy in a heavily pre-treated, Western population of patients with acquired resistance to currently available EGFR inhibitors. Rociletinib is the only EGFR-directed therapy that has been shown to spare wild-type EGFR in clinical studies. Inhibition of wild-type EGFR is associated with cutaneous (and other) toxicities such as acneiform rash, stomatitis and paronychia, all of which may significantly impact patients' quality of life, result in treatment discontinuation and cause patient distress. The Company believes this aspect of rociletinib's clinical profile represents a significant point of differentiation from approved EGFR inhibitors and those currently in clinical development. In May, the U.S. FDAgranted Breakthrough Therapy designation for rociletinib as treatment for mutant NSCLC in patients with the T790M mutation after progression on EGFR-directed therapy.

The next update of rociletinib clinical data will take place at the 26th EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics in Barcelona on November 21.

Data from the TIGER-X study, combined with data from the TIGER-2 study, are expected to serve as the basis of U.S. and E.U. regulatory submissions for rociletinib in mid-2015. The Company is currently enrolling the two Phase 2 expansion cohorts of TIGER-X in EGFR mutant patients with the T790M mutation; the first includes T790M positive patients directly after progression on their first and only tyrosine kinase inhibitor (TKI) therapy, comparable to the TIGER-2 registration study patient population. The second cohort includes later-line T790M positive patients after progression on their second or later TKI therapy or subsequent chemotherapy. The TIGER-2 study, in T790M positive patients directly after progression on their first and only TKI therapy, began enrolling patients earlier in the second quarter. The TIGER-1 study, a randomized Phase 2/3 registration study of rociletinib versus erlotinib in newly-diagnosed EGFR mutant patients has just commenced. In addition, the Company initiated its

Phase 1 study of rociletinib in Japan earlier this year.

In addition, Clovis expects to initiate the TIGER-3 study, a randomized, comparative study of rociletinib versus chemotherapy in T790M positive and T790M negative patients with EGFR-mutant NSCLC and acquired TKI resistance in the next few months.

32. On November 7, 2014, the Company filed a Form 10-Q for the quarter ended September 30, 2014 ("3Q 2014 10-Q") with the SEC, which provided the Company's quarterly financial results. The 3Q 2014 10-Q was signed by Defendants Mahaffy and Mast. The 3Q 2014 10-Q contained signed certifications pursuant to SOX by Defendants Mahaffy and Mast, which stated that the financial information contained in the 3Q 2014 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

33. The 3Q 2014 10-Q discussed rociletinib, stating in relevant part:

Rociletinib (CO-1686)

In May 2010, the Company entered into a worldwide license agreement with Avila Therapeutics, Inc. (now part of Celgene Corporation) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor ("EGFR") gene product. Rociletinib was identified as the lead drug candidate to be developed under the license agreement. The Company is responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib. The Company made an up-front payment of $2.0 million upon execution of the license agreement and is obligated to pay royalties on net sales of rociletinib, based on the volume of annual net sales achieved. Celgene has the option to increase royalty rates by electing to reimburse a portion of the development expenses incurred by the Company. This option must be exercised within a limited period of time after Celgene is notified of our intent to pursue regulatory approval of rociletinib in the U.S. or European Union as a first line therapy. Such notice was provided to Celgene on June 4, 2014, and on September 2, 2014, we received notification from Celgene that the company elected not to exercise this option.

In January 2013, the Company entered into an exclusive license agreement with Gatekeeper Pharmaceuticals, Inc. ("Gatekeeper") to acquire exclusive rights under patent applications associated with mutant EGFR inhibitors and methods of treatment. Pursuant to the terms of the license agreement, the Company made an up-front payment of $250,000 upon execution of the agreement, which was recognized as acquired in-process research and development expense. If rociletinib is approved for commercial sale, the Company will pay royalties to Gatekeeper on future net sales.

In February 2014, the Company initiated a Phase II study for rociletinib which resulted in a $5.0 million milestone payment to Celgene as required by the license agreement. This payment was recognized as acquired in-process research and

development expense. The Company may be required to pay up to an additional aggregate of $110.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company may be required to pay up to an aggregate of $120.0 million in sales milestones if certain annual sales targets are achieved.

34. On November 18, 2015, the Company issued a press release entitled, "Interim Data From Rociletinib (CO-1686) Phase 1/2 Study Shows Compelling and Durable Clinical Activity and Progression-Free Survival (PFS) in Patients with EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)." The press release describes the new data, stating in relevant part:

INTERIM DATA FROM ROCILETINIB (CO-1686) PHASE 1/2 STUDY SHOWS COMPELLING AND DURABLE CLINICAL ACTIVITY AND PROGRESSION-FREE SURVIVAL (PFS) IN PATIENTS WITH EGFR-MUTANT NON-SMALL CELL LUNG CANCER (NSCLC)

- 67% objective response rate (ORR) observed in evaluable heavily-pretreated T790M+ patients treated with 625mg or 500mg BID (clinical dose group)
- Median PFS of 10.4 months in clinical dose group; data continue to mature
- Well-tolerated – majority of treatment-related adverse events are grade 1-2
- In T790M-negative patients treated with 625mg or 500mg BID, 36% ORR and median PFS of 7.5 months observed
- Only TKI shown to spare wild-type EGFR signaling
- U.S. and E.U. regulatory submissions planned in mid-2015

BARCELONA, Spain--(BUSINESS WIRE)--Nov. 18, 2014-- Clovis Oncology (NASDAQ:CLVS) announced today updated findings from its ongoing Phase 2 clinical study of rociletinib (CO-1686), the Company's novel, oral, targeted covalent (irreversible) mutant-selective inhibitor of the epidermal growth factor receptor (EGFR) for the treatment of NSCLC in patients with initial activating EGFR mutations as well as the primary resistance mutation T790M. These data are being presented Friday, November 21 in an oral presentation (Abstract No. LBA 10) by Professor Jean-Charles Soria at the 26th EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, Spain.

"I have been involved in the clinical development of rociletinib since the first patient was dosed, and it is gratifying to see the progress made and the data presented at the ENA Symposium today," said Dr. Jonathan Goldman, Assistant Professor, UCLA Hematology & Oncology, Associate Director of Drug Development and Director of Clinical Trials in Thoracic Oncology. "In particular, the data presented are consistent with my own experience that the 625mg BID dose provides very encouraging efficacy with excellent tolerability. In addition, the early evidence of activity in the T790M negative patients is surprising and may address a remaining unmet medical need for this additional group of patients who have also progressed on initial

TKI therapy."

"These data demonstrate the very encouraging activity and tolerability observed with rociletinib at our go-forward dose of 625mg BID, and our step-down dose of 500mg BID," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We are now expanding beyond our initial focus on T790M-positive patients and are very enthusiastic about our expansion into front-line patients with TIGER-1, and soon, into an all-comer population of patients with acquired TKI resistance, including both T790M-positive and T790M-negative patients with TIGER-3. We are actively preparing for the first of our planned regulatory filings, which include the U.S. NDA and E.U. MAA in mid-2015."

Two Phase 2 expansion cohorts (known as TIGER-X) are currently enrolling in the United States, Europe, and Australia in EGFR mutant patients with the T790M mutation. ***Patients in these cohorts are receiving 625mg BID of the intended commercial tablet formulation of rociletinib, and data from these cohorts will form part of the NDA/MAA submission packages***. The two cohorts include patients with T790M+ disease either after progression on their first and only TKI therapy, or after progression on their second or later TKI therapy or chemotherapy.

Data from 56 T790M-positive patients treated with rociletinib in the clinical dose group – which includes the recommended Phase 2 dose of 625mg BID (n=30) and the step-down dose of 500mg BID (n=26) – are being presented today, together with data from 11 T790M-negative patients treated at the same doses.

Patients in the clinical dose group were heavily pre-treated prior to receiving rociletinib; 79 percent of patients had immediately progressed on TKI therapy prior to rociletinib treatment. The median number of previous lines of therapy across patients was three.

Evidence of Activity

The objective response rate (ORR) in 27 evaluable T790M-positive patients receiving either 625 or 500mg BID was 67%. The ORR was comparable in the 625mg BID and 500mg BID dose groups. The disease control rate was 89% for the clinical dose group, and again, was consistent across doses. The median PFS for the clinical dose group was 10.4 months, with follow-up for some patients exceeding one year.

In 11 evaluable T790M-negative patients treated at 625 or 500mg BID, a 36% ORR and median PFS of 7.5 months were observed. This activity in the non-target T790M-negative patient group is surprising and may, in part, relate to the inhibition of IGF1-R (insulin growth factor receptor 1) by a metabolite of rociletinib. In addition to Clovis' other clinical trials focused on newly-diagnosed EGFR-mutant NSCLC patients in TIGER-1 and T790M-positive patients in TIGER-X and TIGER-2, the Company is now exploring treatment of the T790M-negative population in its TIGER-3 comparative study versus chemotherapy, which includes both T790M-positive and –negative patients. Forty percent of patients who progress on TKI therapy do so for reasons other than the T790M mutation, and this represents a serious unmet medical need.

Safety and Tolerability

Data presented at ENA demonstrate that rociletinib is well-tolerated, with no evidence of systemic wild-type EGFR inhibition. The most common treatment-related adverse events (AEs) reported in ≥15 percent of all patients included: hyperglycemia, diarrhea, nausea, and reduced appetite. Most adverse events were grade 1 or 2 in severity. The only grade 3/4 treatment-related adverse event observed in more than one patient was hyperglycemia (14 percent). Hyperglycemia, when observed and requiring treatment, is typically managed with a commonly-prescribed single oral agent.

CO-1686 Clinical Development

Clovis is currently enrolling several studies in EGFR-mutant NSCLC in addition to the TIGER-X expansion cohorts noted above:

- The TIGER-2 study is currently enrolling patients with EGFR-mutant NSCLC with a centrally-confirmed T790M mutation directly after progression on their first and only TKI therapy. Patients receive rociletinib at the recommended Phase 2 dose (RP2D) of 625mg BID. The primary study endpoint is overall response rate; secondary endpoints include duration of response, progression-free survival, overall survival, and safety. This global study includes, for the first time, patients from Asian countries including South Korea, Taiwan and Hong Kong.
- The TIGER-1 study is a randomized Phase 2/3 registration study of rociletinib vs. erlotinib in newly-diagnosed EGFR-mutant patients. The Phase 2 portion of the study will enroll 200 patients. Upon completion of enrollment of the Phase 2 portion of the study, the Phase 3 portion of the study will immediately follow. The Phase 3 portion is a blinded study and the sizing will be determined in part by the initial data from the Phase 2 portion of the study. Study sites are currently enrolling in the U.S. and will enroll soon in Europe, Australia and Asia.
- The TIGER-3 study is an international, randomized, comparative study of rociletinib versus chemotherapy in T790M-positive and T790M-negative patients with EGFR-mutant NSCLC and acquired TKI resistance, which is expected to initiate in the next few months. As well as measuring efficacy in T790M-positive patients, this study will explore whether rociletinib activity in all-comers, including T790M-negative patients, is superior to single-agent chemotherapy, the current standard of care.
- For more information, please visit www.tigertrials.com.
- In addition, a Phase 1 study of rociletinib is underway in Japan and an expansion cohort is currently enrolling at 625mg BID to confirm a global recommended Phase 2 dose (RP2D).

Data from the TIGER-X expansion cohorts, combined with data from TIGER-2, are expected to serve as the basis of a U.S. NDA and E.U. MAA for rociletinib in mid-2015.

(Emphasis Added).

35. On February 27, 2015, the Company issued a press release entitled, "Clovis Oncology Announced 2014 Operating Results." The press release stated in relevant part:

CLOVIS ONCOLOGY ANNOUNCES 2014 OPERATING RESULTS

- *Rociletinib (CO-1686) NDA and MAA submissions for EGFR-mutant lung cancer planned mid-2015*
- *Rucaparib development program accelerated; filing now planned for treatment of platinum-sensitive ovarian cancer in 2016*

BOULDER, Colo.--(BUSINESS WIRE)--Feb. 25, 2015-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter and year ended December 31, 2014, and provided an update on the Company's clinical development programs for 2015.

"We believe that 2015 will be a transformative year for us, as we prepare to submit our NDA and MAA for rociletinib in advanced EGFR-mutant lung cancer to the U.S. and E.U. regulatory authorities mid-year, and accelerate our pivotal program for rucaparib to enable 2016 submissions for advanced ovarian cancer for BRCA-mutant and for BRCAness patient populations," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "All of this activity builds on what was a very exciting 2014."

2014 Financial Results and 2015 Financial Outlook

Clovis reported a net loss for the fourth quarter of 2014 of $54.9 million ($1.62 per share), and $160.0 million ($4.72 per share) for the year ended December 31, 2014. This compares to a net loss of $29.2 million ($0.92 per share) for the fourth quarter and $84.5 million ($2.95 per share) for the year ended December 31, 2013.

Research and development expenses totaled $50.1 million for the fourth quarter of 2014 and $137.7 million for the full year 2014, compared to $22.5 million for the fourth quarter and $66.5 million for the full year 2013. The increase in expenses for both periods is due to the significantly expanded clinical development activities for rociletinib and rucaparib, increased manufacturing of clinical drug supplies for the rociletinib and rucaparib programs, and increased personnel-related expenses associated with the hiring of additional staff to support the Company's expanded development activities.

General and administrative expenses totaled $5.6 million for the fourth quarter of 2014 and $21.5 million for the full year 2014, compared to $5.5 million for the fourth quarter and $16.6 million for the full year 2013. The modest increase year over year is primarily due to higher share-based compensation expense for employees engaged in general and administrative activities.

In the first quarter of 2014, the Company recorded milestone revenue of $13.6 million received pursuant to our collaboration and license agreement for lucitanib and also recognized charges for acquired in-process research and development

expense totaling$8.4 million associated with milestone payments incurred for rociletinib and lucitanib. An additional charge for acquired in-process research and development expense of $0.4 million was recorded in the second quarter of 2014 related to the achievement of a Phase 2 milestone for rucaparib.

Operating expenses for the fourth quarter of 2014 totaled $53.9 million, and $172.1 million for the full year 2014, inclusive of the acquired in-process research and development expense described above. Total operating expenses include non-cash charges totaling $4.1 million for the fourth quarter and $25.6 million for the full year 2014 for share-based compensation expense, amortization of an intangible asset, and the accretion of contingent purchase consideration associated with the 2013 acquisition of Ethical Oncology Science, S.p.A.

Net cash burn for the fourth quarter of 2014 totaled $34.2 million, and $120.0 million for the full year 2014. As of December 31, Clovis had $482.7 million in cash and cash equivalents and 34.0 million outstanding shares of common stock.

2015 Key Milestones and Objectives

Highlights of planned objectives for each product follows:

Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the primary resistance mutation, T790M, which develops in approximately 60 percent of patients treated with first- and second-generation EGFR inhibitors.

Data presented in late 2014 demonstrated an objective response rate (ORR) of 67 percent in 27 evaluable T790M-positive patients receiving either 625mg or 500mg BID (the clinical dose group). The ORR was comparable in the 625mg BID and 500mg BID dose groups. The disease control rate was 89 percent and was also consistent across doses. The immature median PFS was 10.4 months, with follow-up for some patients exceeding one year. Data presented to date demonstrate that rociletinib is well-tolerated, with no evidence of systemic wild-type EGFR inhibition. The only common grade 3/4 toxicity reported was hyperglycemia (14 percent), which was readily managed with an oral hypoglycemic agent.

In addition, data for 19 T790M-negative patients receiving either 625mg or 500mg BID were presented in January 2015. An ORR of 42 percent was observed in these patients. The immature median PFS was 7.5 months. Based on this observed activity, the Company is now actively exploring rociletinib as treatment for T790M-negative patients, where a significant unmet medical need exists.

Initial data from two single-arm studies (TIGER-X and TIGER-2) are expected to serve as the basis of U.S. and E.U. regulatory submissions for rociletinib in mid-2015. The Company continues to enroll patients in the two Phase 2 expansion

cohorts of TIGER-X in EGFR mutant patients with the T790M mutation.

In addition to TIGER-X, three global registration studies are currently planned or underway as part of the TIGER program:

- TIGER-1, a randomized Phase 2/3 study of rociletinib vs. erlotinib in EGFR mutant patients who have not had TKI therapy, but who may have received one type of chemotherapy;
- TIGER-2, a single-arm study in second-line patients immediately after progression on their first and only TKI therapy, which includes both T790M-positive and T790M-negative cohorts; and
- TIGER-3, a randomized study of rociletinib vs. chemotherapy in later-line patients progressing on second or later TKI or subsequent chemotherapy, which includes both T790M-positive and T790M-negative cohorts.

A Phase 1 study of rociletinib is also underway in Japan and the Company intends to initiate combination studies with several targeted therapeutics and checkpoint inhibitors during 2015; initially, these include planned combinations with PDL1, PD1, MEK and Aurora kinase inhibitors.

36. On February 27, 2015, the Company filed its annual report on Form 10-K for the year ending December 31, 2014 (the "2014 10-K"). The 2014 10-K was signed by Defendants Mahaffy and Mast. The 2014 10-K contained signed certifications pursuant SOX by Defendants Mahaffy and Mast The 2014 10-K discussed rociletinib, stating in relevant part:

> Rociletinib is a novel, oral, small molecule selective covalent inhibitor of the cancer-causing mutant forms of EGFR for the treatment of NSCLC. Rociletinib is being evaluated in a global clinical development program in patients with mutant EGFR NSCLC. Because rociletinib targets both the initial activating EGFR mutations, as well as the primary resistance mutation, T790M, it has the potential to treat NSCLC patients with EGFR mutations both as a first-line or second- or later-line therapy.
>
> In May 2010, we in-licensed rociletinib from Avila Therapeutics, Inc. (now Celgene Avilomics Research Inc., part of Celgene Corporation). In May 2014, rociletinib received "Breakthrough Therapy" designation from the U.S. Food and Drug Administration ("FDA") for the treatment of patients with EGFR mutation-positive NSCLC, whose disease has progressed on prior EGFR-directed therapy due to T790M-mediated acquired drug resistance. We intend to file applications for marketing approvals for rociletinib in the U.S. and E.U. in mid-2015.
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> * * *
>
> *Design of Rociletinib - a Targeted Covalent Drug*

Most human diseases are rooted in the abnormal activity of certain proteins. Traditional small molecule drugs, while able to inhibit disease-causing proteins, are generally only able to form transient binding interactions with the disease targets and are thus considered reversible. A covalent drug, however, forms a strong and durable bond with its protein target, known as a covalent bond. A targeted covalent drug is designed to form its covalent bond in a highly directed and controlled manner with a specific site on the disease target. This directed bond formation is key to achieving a distinct selectivity profile that is difficult to achieve with traditional reversible small molecules. Rociletinib was developed using a proprietary platform to purposefully and systematically design and develop targeted covalent inhibitors.

Rociletinib was designed by identifying a site on the EGFR protein where a covalent bond could be formed and, using proprietary drug design techniques, modeling chemical structures that could selectively form a bond with this site. These molecules were then synthesized and tested in assays to verify their ability to form targeted covalent bonds and to potently inhibit the mutant forms of EGFR and also to demonstrate that covalent bonds were not formed indiscriminately with other targets.

Clinical Development

We designed an accelerated clinical development program for rociletinib and we are pursuing its development as both a second-line or later treatment for EGFR-mutated NSCLC patients who become resistant to TKIs due to the emergence of the T790M mutation, and potentially, as a first-line treatment for EGFR-mutated NSCLC. We are also exploring rociletinib's utility for progressing EGFR-mutated NSCLC patients who do not express the T790M mutation (T790M-negative patients).

We initiated our first Phase I/II study of rociletinib in the first quarter of 2012 in patients with metastatic or unresectable recurrent NSCLC and a documented EGFR mutation. Patients were not required to be T790M positive for the Phase I portion of the study but had to have progressed on prior EGFR-directed TKI therapy (prior chemotherapy was also allowed). The Phase I portion of the study was conducted in the U.S., France and Australia. Data from this study was used to determine the tolerability and pharmacokinetics of rociletinib, as well as provide initial evidence of efficacy.

We are currently enrolling in the U.S., Europe and Australia the Phase II expansion cohorts of the study, designated as TIGER-X under the TIGER **(Third**-generation **I**nhibitor of Mutant E**G**FR in Lung Canc**ER**) program***. These cohorts are testing the efficacy of rociletinib in patients with T790M-positive NSCLC disease, either immediately after progression on their first and only TKI therapy or after progression on their second or later TKI therapy of subsequent chemotherapy. Data presented at a medical conference in late 2014 demonstrated an objective response rate ("ORR") of 67% in 27 evaluable T790M-positive patients receiving either 625mg or 500mg BID. The ORR was comparable in the 625mg BID and 500mg BID dose groups. The disease control rate was 89% and was also consistent across doses.*** Safety data presented

to date demonstrate that rociletinib is well-tolerated, with no evidence of systemic wild-type EGFR inhibition. Most adverse events were grade 1 or 2 in severity; the only grade 3/4 treatment-related adverse event observed in more than one patient was hyperglycemia (14 percent). Hyperglycemia, when observed and requiring treatment, is typically managed with an oral anti-hyperglycemic agent.

In addition to TIGER-X, three global studies are currently included as part of the TIGER program:

- TIGER-1, a randomized Phase II/III study of rociletinib vs. erlotinib in EGFR mutation-positive patients who have not had TKI therapy, but who may have received one type of chemotherapy;
- TIGER-2, a single-arm study in second-line patients immediately after progression on their first and only TKI therapy, which includes both T790M-positive and T790M-negative cohorts; and
- TIGER-3, a randomized study of rociletinib vs. chemotherapy in later-line patients progressing on second or later TKI or subsequent chemotherapy, which includes both T790M-positive and T790M-negative cohorts.

The primary endpoints of TIGER-2 and TIGER-3 will be ORR. If the data from the Phase II portion of the TIGER-1 study are positive, we intend to transition into the Phase III portion of the study to evaluate rociletinib as a first-line therapy for NSCLC patients with activating mutations of EGFR, with progression-free survival as the primary endpoint of the study. In addition, a Phase I study of rociletinib is underway in Japan.

Data from the TIGER-X cohorts, combined with data from TIGER-2, are expected to form the basis of an NDA in the U.S. and an E.U. Marketing Approval Application ("MAA") planned for mid-2015 to seek the initial approvals for rociletinib for the treatment of second-line EGFR mutant NSCLC in patients with the T790M mutation.

(Emphasis added).

37. On May 6, 2015, the Company issued a press release entitled, "Clovis Oncology Announced First Quarter 2015 Operating Results." The press release stated in relevant part:

CLOVIS ONCOLOGY ANNOUNCES FIRST QUARTER 2015 OPERATING RESULTS

- *Rociletinib (CO-1686) rolling NDA submission for EGFR-mutant lung cancer expected to commence in June, and complete by July/August*
- *Launch planning underway for potential late 2015 U.S. launch of rociletinib*

- *Phase 1/2 rociletinib data published in April 30 issue of the New England Journal of Medicine*
- *Rucaparib granted Breakthrough Therapy designation in April*
- *NDA filing for rucaparib planned for treatment of advanced ovarian cancer in 2016*
- *Oral presentations for rociletinib and rucaparib at ASCO 2015*

BOULDER, Colo.--(BUSINESS WIRE)--May 6, 2015-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter ended March 31, 2015, and provided an update on the Company's clinical development programs for 2015.

"2015 is proving to be a very exciting and important year for us, as we are preparing our near-term regulatory submissions seeking approval in the U.S. and E.U. for rociletinib in advanced EGFR-mutant lung cancer and planning for our first commercial launch by year-end. We are also pleased to have substantially accelerated the development of rucaparib in both mutant BRCA and the broader BRCA-like population for advanced ovarian cancer, with an NDA submission planned for 2016," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "The extremely compelling results for rucaparib to date in mutant BRCA ovarian cancer were also recognized by the FDA, resulting in our second product receiving Breakthrough Therapy designation."

First Quarter 2015 Financial Results

The Company reported no revenues for the first quarter of 2015, compared to $13.6 million for the first quarter of 2014 which consisted of a milestone payment pursuant to its collaboration and license agreement for lucitanib with Les Laboratoires Servier (Servier), earned as a result of the expiration of the opposition period of a lucitanib European patent.

Research and development expenses totaled $56.8 million for the first quarter of 2015, compared to $24.2 million for the first quarter 2014. The increase in expenses is due to the significantly expanded clinical development activities for rociletinib and rucaparib, increased launch planning activities for rociletinib and increased personnel-related expenses associated with the hiring of additional staff to support the Company's expanded activities.

General and administrative expenses totaled $6.8 million for the first quarter of 2015, compared to $5.3 million for the first quarter of 2014. The year over year increase is primarily due to higher share-based compensation expense for employees engaged in general and administrative activities and increased facility costs.

Total operating expenses for the first quarter of 2015 were $64.2 million, compared to $42.1 million for the first quarter of 2014. Operating expenses for the first quarter of 2014 are inclusive of $8.4 million acquired in-process research and development expenses associated with milestone payments incurred

for rociletinib and lucitanib and $3.4 million of amortization expense of an intangible asset.

Net loss attributable to common shareholders was $63.1 million, or $1.86 per share, for the first quarter of 2015 compared to a net loss of $30.7 million, or $0.91 per share, for the first quarter of 2014. Net loss for the first quarter of 2015 included share-based compensation expense of $8.7 million compared to $4.9 million for the first quarter of 2014.

Clovis had $433.4 million in cash, cash equivalents and available-for-sale securities and approximately 34.1 million outstanding shares of common stock as of March 31, 2015.

2015 Key Milestones and Objectives

Highlights of planned objectives for each product follows:

Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the dominant acquired resistance mutation, T790M, which develops in approximately 60 percent of patients treated with first- and second-generation EGFR inhibitors.

Initial data from two single-arm studies (TIGER-X and TIGER-2) are expected to serve as the basis of U.S. and E.U. regulatory submissions for rociletinib during 2015. The rolling NDA submission to the FDA for advanced EGFR-mutant NSCLC is expected to commence in June and complete in July or August of 2015.

In addition to TIGER-X, three global registration studies are currently enrolling as part of the TIGER program:

- TIGER-1, a randomized Phase 2/3 study of rociletinib vs. erlotinib in newly diagnosed EGFR mutant lung cancer patients;
- TIGER-2, a single-arm study in second-line patients immediately after progression on their first and only TKI therapy, which includes both T790M-positive and T790M-negative cohorts; and
- TIGER-3, a randomized study of rociletinib vs. chemotherapy in later-line patients progressing on second or later TKI or subsequent chemotherapy, which includes both T790M-positive and T790M-negative cohorts.

The Phase 1 study of rociletinib in Japan has completed enrollment and a Phase 2 study in Japanese patients, agreed upon with Japanese regulatory authorities, is expected to initiate in the second half of 2015. In addition, the Company is exploring combination studies with several targeted therapeutics and checkpoint inhibitors and expects that three of these combinations – with inhibitors of PD-

L1, PD-1 and MEK – will initiate during the second half of 2015.

Data from the Phase 1/2 study of rociletinib (TIGER-X) were published in the April 30 edition of the *New England Journal of Medicine*. The manuscript included data on the 130 patients enrolled as of June 2014; all had received at least one prior line of EGFR TKI therapy. The patient population was heavily pretreated with very advanced disease; the median number of prior therapies was four, and 72 percent of the patients were taking an EGFR TKI at the time of consent. Fifty percent of patients (65/130) had three or more sites of metastatic disease, and 44 percent had a history of brain metastases (57/130). In the forty-six evaluable patients who possessed the T790M mutation and were treated with a therapeutic dose of rociletinib, overall response rate (ORR) was 59 percent, and immature median progression-free survival (PFS) was 13.1 months. In the 17 evaluable patients who tested negative for the T790M mutation and were treated with a therapeutic dose, the ORR was 29 percent and immature median PFS was 5.6 months. Treatment-related adverse events (AEs) were generally infrequent and mild, and the predominant grade 3 AE was hyperglycemia, occurring in 22 percent of patients treated with efficacious doses (n=92). These data continue to mature.

The next update of clinical data from the ongoing TIGER studies will be presented in an oral presentation at the 2015 American Society of Clinical Oncology Annual Meeting.

38. On May 8, 2015, the Company filed a Form 10-Q for the quarter ending March 31, 2015 ("1Q 2015 10-Q") with the SEC, which provided the Company's quarterly financial results. The 1Q 2015 10-Q was signed by Defendants Mahaffy and Mast. The 1Q 2015 10-Q contained signed certifications pursuant SOX by Defendants Mahaffy and Mast, which stated that the financial information contained in the 1Q 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

39. The 1Q 2015 10-Q discussed rociletinib, stating in relevant part:

Rociletinib (CO-1686)

In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research, Inc., part of Celgene Corporation ("Celgene")) to discover, develop and commercialize a covalent inhibitor of mutant forms of the epidermal growth factor receptor ("EGFR") gene product. As a result of the collaboration contemplated by the agreement, rociletinib was identified as the lead inhibitor candidate, which we are developing under the terms of the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib. We made an up-front payment of $2.0 million upon execution of the license agreement, a $4.0 million milestone payment in the first quarter of 2012 upon acceptance by the U.S. Food and Drug Administration of our Investigational New Drug application for rociletinib and a $5.0 million

milestone payment in the first quarter of 2014 upon initiation of the Phase II study for rociletinib. We recognized all payments as acquired in-process research and development expense.

We are obligated to pay royalties on net sales of rociletinib, based on the volume of annual net sales achieved. The Company is required to pay up to an additional aggregate of $110.0 million in development and regulatory milestone payments if certain clinical study objectives and regulatory filings, acceptances and approvals are achieved. In addition, the Company is required to pay up to an aggregate of $120.0 million in sales milestone payments if certain annual sales targets are achieved.

40. On July 1, 2015, the Company issued a press release after-hours entitled "Clovis Oncology Initiates Rolling NDA Submission to the FDA For Rociletinib In The Treatment of Advanced EGFR-Mutant Non-Small Cell Lung Cancer." The press release contained information on rociletinib and the Company's submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA"), stating in relevant part:

CLOVIS ONCOLOGY INITIATES ROLLING NDA SUBMISSION TO THE FDA FOR ROCILETINIB IN THE TREATMENT OF ADVANCED EGFR-MUTANT NON-SMALL CELL LUNG CANCER

NDA submission is expected to complete by late July

BOULDER, Colo.--(BUSINESS WIRE)--Jul. 1, 2015--

Clovis Oncology, Inc. (NASDAQ: CLVS) ***announced today that it has commenced the submission of a New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rociletinib*** for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test. Rociletinib is the Company's novel, oral targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M.

Rociletinib was granted Breakthrough Therapy designation by the FDA in May 2014. Clovis agreed with FDA that the submission would be a rolling NDA and has filed the first component for potential accelerated approval of rociletinib in the U.S. ***The rolling NDA allows completed portions of an NDA to be submitted and reviewed by the FDA on an ongoing basis. The Company intends to complete the NDA submission by late July 2015***.

"***The initiation of this rolling submission represents a very important first step toward our biggest milestone of 2015 – the submission of our first NDA for rociletinib as treatment for patients with T790M-positive EGFR-mutant non-small cell lung cancer,***" said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We look forward to completing the NDA by the end of July, and are

actively preparing for our first commercial launch."

In addition, the Company intends to complete the Marketing Authorization Application (MAA) for rociletinib to the European Medicines Agency at the end of July.

About Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the dominant acquired resistance mutation, T790M, which develops in approximately 60 percent of patients treated with first- and second-generation EGFR inhibitors, while sparing wild-type, or "normal" EGFR at anticipated therapeutic doses. Accordingly, it has the potential to treat NSCLC patients with EGFR mutations both as a first-line or second-line treatment with a potentially reduced toxicity profile. Rociletinib was granted Breakthrough Therapy designation by the U.S. FDA inMay 2014.

About Rociletinib Clinical Development

Clovis is currently enrolling several studies in EGFR-mutant NSCLC:

- ***TIGER-X is a Phase 1/2 study designed to evaluate the safety and efficacy of three different doses of rociletinib in a very advanced patient population.***
- TIGER-1 is a randomized Phase 2/3 registration study versus erlotinib in newly-diagnosed patients.
- TIGER-2 is a global registration study underway in both T790M-positive and T790M-negative patients directly after progression on their first and only TKI therapy.
- TIGER-3 is a randomized, comparative study versus chemotherapy in both T790M-positive and T790M-negative patients with acquired TKI resistance.
- A Phase 1 study of rociletinib in Japan has completed enrollment and a Phase 2 study in Japanese patients, agreed upon with Japanese regulatory authorities, is expected to initiate in the second half of 2015.
- Multiple combination studies are planned to initiate in the second half of 2015, including inhibitors of PD-L1, PD-1 and MEK.
- For more information, please visit www.tigertrials.com.

(Emphasis added).

41. On August 3, 2015, the Company issued a press release entitled, "Clovis Oncology Completes U.S. and E.U. Regulatory Submissions for Rociletinib for the Treatment of Advanced EGFR-Mutant T790M+ Non-Small Cell Lung Cancer." The press release discussed the submission of the NDA for rociletinib to the FDA, stating in relevant part:

CLOVIS ONCOLOGY COMPLETES U.S. AND E.U. REGULATORY

SUBMISSIONS FOR ROCILETINIB FOR THE TREATMENT OF ADVANCED EGFR-MUTANT T790M+ NON-SMALL CELL LUNG CANCER

New Drug Application submitted to U.S. Food and Drug Administration and Marketing Authorization Application submitted toEuropean Medicines Agency

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 3, 2015-- ***Clovis Oncology, Inc. (NASDAQ: CLVS) announced today that it has submitted its New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rociletinib*** for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test. Rociletinib is the Company's novel, oral targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M. Rociletinib was granted Breakthrough Therapy designation by the U.S. FDA in May 2014.

In addition, Clovis has also submitted its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) through the centralized procedure for rociletinib for the treatment of adult patients with mutant EGFR NSCLC who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation.

There is a validation period before both applications are formally accepted, after which the review commences.

"***The submissions of our first NDA and MAA for rociletinib represent a major step forward for our company***," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "These two submissions – completed on the same day, no less -- were made possible through the tremendous commitment and hard work of Clovis employees and our clinical collaborators at leading U.S. and international academic institutions over the last many months, and I am grateful for their tireless efforts. We are actively preparing for what we hope to be our first U.S. commercial launch, and the opportunity to address the needs of patients with T790M-positive EGFR-mutant non-small cell lung cancer. We are also actively building our commercial organization in Europe to prepare for a potential launch next year."

QIAGEN, Clovis' companion diagnostic partner, intends to file a supplemental PMA application of its approved *therascreen* EGFRtest with the FDA to allow for regulatory approval of the companion diagnostic concurrent with rociletinib approval. Analytical performance of the *therascreen* EGFR test has been established for 21 EGFR mutations, including the most prevalent resistance mutation, T790M. The test supports efficient laboratory workflow with real-time PCR technology on the FDA approved Rotor-Gene Q MDx, which is part of QIAGEN's QIAsymphony family of laboratory solutions.

(Emphasis added).

42. On August 6, 2015, the Company issued a press release entitled "Clovis Oncology Announces Second Quarter 2015 Operating Results." The press release stated in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES SECOND QUARTER 2015 OPERATING RESULTS
>
> - ***Completed rociletinib (CO-1686) U.S. NDA and E.U. MAA regulatory submissions in July for patients with EGFR-mutant non-small cell lung cancer who have been previously treated with an EGFR-targeted therapy and have the T790M mutation***
> - ***Preparing for potential Q4 2015 U.S. launch of rociletinib****; establishing European commercial organization for potential 2016 launch of rociletinib*
> - *Raised $298 million in July equity offering; June 30, 2015 pro forma cash and available-for-sale securities balance of $676 million*
>
> BOULDER, Colo.--(BUSINESS WIRE)--Aug. 6, 2015-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter ended June 30, 2015, and provided an update on the Company's clinical development programs for 2015.
>
> ***"This is a very exciting time for our company," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We have completed our first rociletinib NDA and MAA submissions, we are building out our commercial organizations in both the U.S. and E.U., and we are preparing for a potential U.S. launch as early as the end of this year. We are quickly accelerating toward becoming a global commercial biopharmaceutical organization."***
>
> **Second Quarter 2015 Financial Results**
>
> The Company reported no revenues for the second quarter and first half of 2015, compared to $13.6 million for the first quarter and first half of 2014 which consisted of a milestone payment pursuant to its collaboration and license agreement for lucitanib with Les Laboratoires Servier (Servier).
>
> Research and development expenses totaled $60.4 million for the second quarter of 2015 and $117.1 million for the first half of 2015, compared to $28.4 million and $52.6 million for the comparable periods in 2014. ***The increase in expenses for both the three- and six-month periods is due to the significantly expanded clinical development activities for rociletinib and rucaparib, increased launch planning activities for rociletinib and increased personnel-related expenses associated with the hiring of additional staff to support the Company's expanded activities.***
>
> General and administrative expenses totaled $7.2 million for the second quarter of 2015 and $14.0 million for the first half of 2015, compared to $5.3 million and $10.6 million for the comparable periods in 2014. The year over year increase is primarily due to higher share-based compensation and personnel expense for employees engaged in general and administrative activities, increased facility costs and higher professional service fees.

Net loss attributable to common shareholders was $71.5 million ($2.10 per share) for the second quarter of 2015 and $134.7 million ($3.96 per share) for the first half of 2015, compared to a net loss of $34.8 million ($1.03 per share) and $65.5 million ($1.93per share) for the comparable periods of 2014. Share-based compensation expense totaled $8.4 million for the second quarter of 2015 and $17.1 million for the first half of 2015.

Clovis had $377.6 million in cash, cash equivalents and available-for-sale securities and approximately 34.1 million outstanding shares of common stock as of June 30, 2015. In July 2015, the Company raised net proceeds of $298.0 million through an offering of 4.1 million shares of common stock.

2015 Key Milestones and Objectives

Highlights of planned or completed objectives for each product follows:

Rociletinib

Rociletinib is an oral, potent, mutant-selective inhibitor of epidermal growth factor receptor (EGFR) under investigation for the treatment of EGFR-mutated non-small cell lung cancer (NSCLC). Rociletinib targets the activating mutations of EGFR (L858R and Del19), while also inhibiting the dominant acquired resistance mutation, T790M. The T790M mutation develops in approximately 60 percent of patients treated with first- and second-generation EGFR inhibitors.

On July 30, 2015, the Company submitted its New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) for rociletinib for the treatment of patients with mutant EGFR NSCLC who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test. ***Rociletinib was granted Breakthrough Therapy designation by the U.S. FDA in May 2014***. Clovis also submitted its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) through the centralized procedure for rociletinib for the same indication. There is a validation period before both applications are formally accepted, after which the review commences.

The U.S. and E.U. regulatory submissions include data from two single-arm studies, TIGER-X and TIGER-2. During the second quarter, updated findings from the TIGER-X study, evaluating the safety and activity of rociletinib in a very advanced EGFR-mutant NSCLC patient population were presented at the 2015 American Society of Clinical Oncology (ASCO) annual meeting.

Highlights of the data presented included the following:

- 60% overall response rate (ORR) and 90% disease control rate (DCR) in heavily pretreated centrally confirmed tissue T790M-positive patients at the 500mg BID dose
- Median progression free survival (PFS) of 10.3 months observed in patients without a history of CNS metastases; median PFS of 8 months observed in an overall population of 270 heavily pretreated centrally confirmed tissue T790M-positive patients, including 40% of patients with a history of CNS metastases
- 37% ORR in centrally confirmed tissue T790M-negative patients

- 57% ORR and 80% DCR in centrally confirmed plasma-genotyped T790M-positive patients – may allow for broader testing for mutations in patients ineligible for tissue biopsy
- Well-tolerated; the most frequent adverse reactions or lab abnormalities reported were diarrhea, nausea, fatigue, QTc prolongation and hyperglycemia; the only Grade 3 adverse reaction or lab abnormality reported in greater than 5% of patients was hyperglycemia

(Emphasis added).

43. That same day, the Company held a conference call to discuss the second quarter of 2015 earnings. Defendant Mahaffy discussed rociletinib, stating in relevant part:

> Certainly an exciting time here. ***We have completed regulatory submissions on schedule for rociletinib in U.S. and Europe and we are preparing for the potential U.S. commercial launch for rociletinib before year end.***
>
> We also established a five-year Cooperative Research and Development Agreement known as CRADA with the NCI to explore rociletinib anticancer combination therapy which will complement our own combination study plan.
>
> We are also making great progress with rucaparib. In April we received breakthrough therapy designation for rucaparib for advanced mutant BRCA ovarian cancer and at ASCO this year we have provide an updated data in both mutant BRCA, as well as BRCA-like patients, which I will describe shortly.
>
> Importantly, with the $298 million equity offering we completed in July, we are well-capitalized to pursue our development and clinical objectives. ***The breakthrough therapy designation in place for two of the three products in our pipeline and the potential U.S approval for rociletinib by year end 2015*** and rucaparib in 2016, clearly accelerating for becoming a commercial biopharmaceutical company.
>
> * * *
>
> Let me start with rociletinib, as mentioned our regulatory filings took place in U.S. and Europe before the end of July. There is a validation period before both applications are firmly accepted for review and ***we anticipate receiving the validation for these filings during the third quarte***r. We are also pleased that in July, the EMA granted rociletinib accelerated assessment which can reduce the EMA review time by approximately three months.
>
> QIAGEN supplemental PMA filing for companion diagnostic for T790M positive mutant EGFR non-small cell lung cancer is expected to be submitted in the next few days and we expect that it will be reviewed in parallel with our NDA submission.

I'd like to take a moment to recognize the team that work so tirelessly to submit these simultaneous filings. It was a huge effort by our pretty small organization and our clinical collaborators, and I am proud and impressed that we able to go from IND to NDA in just over three years, ahead of our most optimistic expectations from the start of this program.

Our submissions include data from two single-arm studies, TIGER-X and TIGER-2. These data sets have continued to demonstrate compelling and consistent activity, and tolerability in patient of T790M-positive mutant EGFR non-small cell lung cancer.

I would like to take a moment to review some of the specific characteristics of our data set. Our data are derived primarily from Western patients who are heavily pretreated and have very advanced diseases.

As reported at ASCO, patients at the 500 milligram BID dose enrolled in our studies had received a median of three prior therapies, 74% had progressed on an immediate prior EGFR TKI and 40% had a history of brain metastases, 84% of these patients were treated at U.S. institutions, primarily academic institutions.

These patients we believe are representative of the heavily pretreated patients typically seen at U.S. academic cancer centers and given their advanced disease represented real test for a novel therapeutic.

Our data also show that rociletinib treatment is not associated with the cutaneous toxicity, which are the hallmark of wild-type EGFR inhibition, such as acting from rash, stomatitis and paronychia.

All of these can significantly impact patients quality of life, result in treatment discontinuation and cause patient distress, which maybe especially and if you, for patients transitioning to a subsequent treatment following frontline therapy where these side effects occur frequently.

Overall rociletinib is well-tolerated. The most frequent adverse reaction or lab abnormalities reported were diarrhea, nausea, fatigue, QTC prolongation and hyperglycemia.

Importantly, the only Grade 3 adverse reaction or lab abnormality reported in greater than 5% of patients was hyperglycemia. As a result, we believe our data demonstrate the safety and activity of rociletinib in a uniquely relevant patient population.

Interestingly, as we have discussed previously, we have shown encouraging response rates in the centrally confirmed T790M negative patient population as well. This activity maybe related to the anti-IGF1R activity from the human metabolite rociletinib, which of course, is also the cause of the hyperglycemia we sometime see.

Multiple studies in recent years, most recently by Crystal et al. in science have been published demonstrating that the IGF1R pathway plays a role in the development of resistant to EGFR inhibitors and two other targeted therapies.

This unexpected but potentially very meaningful finding is now being explored in our TIGER-2 and TIGER-3 studies where we are actively enrolling both T790M negative and T790M positive patients. This brings me briefly to our ongoing development program for rociletinib.

We have three global registration studies enrolling in the TIGER program in EGFR mutant non-small cell lung cancer patient. TIGER-1, a randomized Phase 2/3 global registration study versus erlotinib in newly diagnosed patients., TIGER-2 single arm study in second line patients directly after progression on their first only TKI therapy. Importantly, TIGER-2 includes both T790M positive and T790M negative patient cohorts and includes sites in the U.S., Europe and Asia.

TIGER-3, a randomized comparative study versus chemotherapy in both T790M positive and T790M negative patients which requires TKI therapy. Phase 1 study of rociletinib in Japan has completed enrollment in [TIGER-J] [ph] the phase 2 study in Japanese patients has agreed upon with the Japanese regulatory authority who will initiate in the fourth quarter and will examine activity in both T790M negative and T790M positive patients.

Finally, as we have discussed, having demonstrated the monotherapy activity of rociletinib, we are now moving forward with the series of combination studies to see if these results can be approved upon. We expect that three of these combinations with inhibitors of PDL1, PD1 and MEK will initiate in the third or fourth quarter of 2015.

We also anticipate additional combination studies beginning in 2016 and will provide details on additional combination studies as we've agreements and protocols in place. To facilitate and potentially accelerate this exploration, we signed a cooperative research and development agreement or CRADA during the second quarter with NCI to evaluate rociletinib in combination with other anticancer therapies over the next five years.

This research will be conducted through the Cancer Therapy Evaluation Program or CTEP of the NCI. We were honored that rociletinib was chosen to participate in this program. ***Importantly, we expect our next updated clinical data to take place at the World Lung Meeting in Denver in September.***

Planned presentations include updated data in T790M negative patient and patients with CNS involvement and many preclinical combinations. As you know and probably have seen, we just presented a full update of our data set at ASCO. ***We do not plan to provide full clinical data update from T790M positive patients in TIGER-X or TIGER-2 trial during the rociletinib regulatory review process. And thus they will not be there at the World Lung Meeting.***

Moving to our commercial plans for rociletinib, we continue to prepare for potential U.S. launch by year-end. Our marketing -- market access, sales

> leadership and U.S. MSL teams are in place. Recruiting the leadership of our field sales organization has also completed with that team in place and we've been extremely pleased with the quality of candidates who have joined us to build a world-class oncology commercial organization here at Clovis. We are now finalizing the recruitment of our sales force and expect to have the full U.S. commercial team including that sales force in place next month.
>
> (Emphasis added).

44. On August 7, 2015, the Company filed a Form 10-Q for the quarter ending June 30, 2015 ("2Q 2015 10-Q") with the SEC, which provided the Company's quarterly financial results. The 2Q 2015 10-Q was signed by Defendants Mahaffy and Mast. The 2Q 2015 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Mahaffy and Mast, which stated that the financial information contained in the 2Q 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

45. The 2Q 2015 10-Q discussed the NDA for rociletinib, stating in relevant part:

> In July 2015, the Company submitted a New Drug Application ("NDA") regulatory filing and a Marketing Authorization Application ("MAA") for rociletinib to the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"), respectively. See Note 15 for discussion of the related milestone payment.
>
> * * *
>
> **15. Subsequent Events**
>
> In July 2015, the Company sold 4,054,487 shares of its common stock in a public offering at $78.00 per share. The net proceeds to the Company from the offering were approximately $298 million, after deducting underwriting discounts and commissions and estimated offering expenses payable.
>
> In July 2015, the Company submitted a NDA and a MAA for rociletinib to the FDA and the EMA, respectively. Under the terms of the license agreement, the Company will make a $12.0 million milestone payment to Celgene within 10 days of acceptance of the filings by the respective agencies, which will be recorded as acquired in-process research and development expense.

46. On August 11, 2015, the Company issued a press release entitled "Clovis Oncology Enters Into Clinical Trial Collaboration." The press release details of a collaboration with Genentech, stating in relevant part:

> CLOVIS ONCOLOGY ENTERS INTO CLINICAL TRIAL COLLABORATION

Study to evaluate the combination of rociletinib (CO-1686) with Genentech's atezolizumab (MPDL3280A) for patients with advanced EGFR-mutant non-small cell lung cancer

BOULDER, Colo.--(BUSINESS WIRE)--Aug. 11, 2015-- Clovis Oncology, Inc. (NASDAQ: CLVS) ***announced today that they have entered into a clinical trial collaboration with Genentech, a member of the Roche Group to evaluate a novel combination therapy of Genentech's investigational cancer immunotherapy atezolizumab (MPDL3280A; anti-PDL1) and rociletinib for the treatment of advanced EGFR-mutant non-small cell lung cancer (NSCLC).*** Rociletinib is the Company's novel, oral targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M.

The Phase 1b/2 trial of rociletinib in combination with atezolizumab is planned to begin enrolling patients before the end of 2015. The trial, which is sponsored by Clovis, is designed to assess the safety and activity of the combination in patients with activating EGFR mutation-positive (EGFRm) advanced or metastatic NSCLC. The Phase 1b portion of the trial will evaluate the safety, tolerability and pharmacokinetics of the combination in this population. The Phase 2 portion of the trial will evaluate the activity of the combination in two subgroups of patients with EGFR-mutant advanced or metastatic NSCLC: those who have not previously received an EGFR TKI or chemotherapy, and those who have progressed on a prior EGFR TKI. T790M-negative and T790M-positive patients will be enrolled in the Phase 1b portion of the trial and in the Phase 2 portion of the trial in the subgroup of patients who have progressed on a prior EGFR TKI. While patients' tumors are not required to express PD-L1 to enroll in the study, PD-L1 expression will be assessed in archival and/or fresh tissue as part of the study.

"We are delighted to evaluate atezolizumab with rociletinib to explore whether the combination can add to the clinical benefit in patients with mutant EGFR non-small cell lung cancer," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "In particular, we are very enthusiastic to explore the potential of this combination in both newly-diagnosed patients as well as those previously treated with TKI therapy."

Rociletinib was granted Breakthrough Therapy designation by the FDA in May 2014. Clovis announced on August 3 that it submitted its New Drug Application (NDA) regulatory filing to the U.S. Food and Drug Administration (FDA) and submitted its Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) through the centralized procedure for rociletinib for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy.

(Emphasis added).

47. On September 4, 2015, the Company issued a press release entitled "Clovis Oncology Announces Data Presentations at 16th World Conference on Lung Cancer." The press

release announced that Clovis would be conducting several presentations on rociletinib, stating in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES DATA PRESENTATIONS AT 16TH WORLD CONFERENCE ON LUNG CANCER
>
> *Four rociletinib mini-oral presentations and two scientific posters debuting at World Conference on Lung Cancer in Denver*
>
> BOULDER, Colo.--(BUSINESS WIRE)--Sep. 4, 2015-- ***Clovis Oncology (NASDAQ:CLVS) today announced that rociletinib, the company's oral targeted covalent (irreversible) mutant-selective inhibitor of epidermal growth factor receptor (EGFR) in development for the treatment of EGFR-mutated, T790M positive non-small cell lung cancer (NSCLC), is the subject of four mini-oral presentations and two poster sessions at the 16th World Conference on Lung Cancer.*** Hosted by the International Association for the Study of Lung Cancer (IASLC), the conference will take place September 6-9, 2015 in Denver.
>
> "***We look forward to sharing updated data from the pivotal TIGER-X trial, analyzing the clinical activity of rociletinib in multiple subsets of patients with advanced EGFR mutant NSCLC, specifically in those with a history of CNS metastases, as well as in patients with T790M negative disease***," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "***The coming months are shaping up to be a very busy and important time for rociletinib, as we move forward with our pivotal TIGER clinical trial program and prepare for potential product launches in both the United States and Europe***."
>
> (Emphasis added).

48. On September 29, 2015, the Company issued a press release entitled "Clovis Oncology Announces U.S. and E.U. Regulatory Milestones for Rociletinib in the Treatment of Advanced EGFR-Mutant T790M+ Non-Small Cell Lung Cancer." The press release discusses regulatory milestones for rociletinib, stating in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES U.S. AND E.U. REGULATORY MILESTONES FOR ROCILETINIB IN THE TREATMENT OF ADVANCED EGFR-MUTANT T790M+ NON-SMALL CELL LUNG CANCER
>
> - ***FDA Grants Priority Review Status to Rociletinib New Drug Application; Assigns Action Date of March 30, 2016***
> - *EMA Accepts Marketing Authorization Application for Rociletinib; Awards Accelerated Assessment*
>
> BOULDER, Colo.--(BUSINESS WIRE)--Sep. 29, 2015-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced ***two major regulatory milestones for***

> ***rociletinib***, its investigational therapy for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation. ***The U.S. Food and Drug Administration (FDA) has accepted Clovis's New Drug Application (NDA) for rociletinib and has granted it priority review status with a Prescription Drug User Fee Act (PDUFA) action date of March 30, 2016.***
>
> Additionally, the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for rociletinib. Europe's Committee for Medicinal Products for Human Use (CHMP) granted Clovis an accelerated assessment for the drug, which reduces the time limit for CHMP to reach an opinion from 210 days to 150 days. Accelerated assessment is granted in recognition of the likelihood that a therapeutic will be of major public health interest in the EU, given the importance of therapeutic innovation in a patient population that exhibits a high unmet need.
>
> Rociletinib is the company's novel, oral, targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M. ***Data from both the pivotal, single-arm TIGER-X and TIGER-2 clinical trials served as the basis for the U.S. and EU regulatory submissions for the treatment of advanced mutant EGFR T790M-positive lung cancer. Rociletinib was given Breakthrough Therapy designation by the FDA in May 2014***.

(Emphasis added).

49. On November 5, 2015, the Company issued a press release entitled "Clovis Oncology Announces Third Quarter 2015 Operating Results." The press release contained information regarding rociletinib, stating in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES THIRD QUARTER 2015 OPERATING RESULTS
>
> - ***New Drug Application (NDA) for rociletinib for the treatment of advanced EGFR-mutant T790M+ non-small cell lung cancer (NSCLC) on file with U.S. FDA***
> - *Marketing Authorization Application (MAA) for rociletinib on file in E.U.; action expected mid-2016*
> - *Raised $298 million in July equity offering*
> - *Enrollment now complete in mutant BRCA population required for U.S. NDA submission for rucaparib in advanced ovarian cancer*
> - *Rucaparib U.S. NDA submission planned Q2 2016*
> - *Erle Mast, Clovis' Chief Financial Officer, announces his retirement effective March 31, 2016*

BOULDER, Colo.--(BUSINESS WIRE)--Nov. 5, 2015-- Clovis Oncology, Inc. (NASDAQ:CLVS) reported financial results for its quarter ended September 30, 2015, and provided an update on the Company's clinical development programs for 2015.

"***We are entering a new phase at Clovis, transitioning into becoming a commercial biopharmaceutical company***," said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "Our U.S. commercial organization, including the sales force, is now fully in place. ***This team is highly experienced, enthusiastic and ready to go, following our U.S. launch meeting last week. We are now fully prepared to launch rociletinib upon a potential U.S. approval and we are actively building our E.U. commercial organization in preparation for a late 2016 launch in Europe***. Additionally, having advanced our rucaparib NDA submission timeline to Q2 2016, we are planning for a potential U.S. launch of rucaparib for advanced ovarian cancer by the end of 2016. ***We are very enthusiastic about the prospect of having our commercial organization support sales for both rociletinib*** and rucaparib."

Third Quarter 2015 Financial Results

Net loss attributable to common shareholders was $98.6 million ($2.62 per share) for the third quarter of 2015 and $233.3 million($6.62 per share) for the first nine months of 2015, compared to a net loss of $39.6 million ($1.17 per share) and $105.1 million($3.10 per share) for the comparable periods of 2014.

Research and development expenses totaled $76.1 million for the third quarter of 2015 and $193.3 million for the first nine months of 2015, compared to $35.0 million and $87.6 million for the comparable periods in 2014. ***The increase in expenses for both the three- and nine-month periods is due to the significantly expanded clinical development activities for rociletinib*** and rucaparib, ***increased launch planning activities for rociletinib and increased personnel-related expenses associated with the hiring of additional staff to support the Company's expanded activities.***

General and administrative expenses totaled $8.3 million for the third quarter of 2015 and $22.3 million for the first nine months of 2015, compared to $5.3 million and $15.9 million for the comparable periods in 2014. The year over year increase is primarily due to higher share-based compensation and personnel expense for employees engaged in general and administrative activities, increased facility costs and higher professional service fees.

Acquired in-process research and development expenses totaled $12.0 million for both the third quarter of 2015 and the first nine months of 2015. There was no acquired in-process research and development expense for the third quarter of 2014 and $8.8 million for the first nine months of 2014. ***During the third quarter of 2015, the Company made milestone payments totaling $12.0 million to Celgene Corporation upon acceptance of the NDA and MAA submissions for rociletinib by the FDA and EMA, respectively.***

Share-based compensation expense totaled $12.4 million for the third quarter of 2015 and $29.5 million for the first nine months of 2015.

> Clovis had $605.9 million in cash, cash equivalents and available-for-sale securities and approximately 38.3 million outstanding shares of common stock as of September 30, 2015. Our net cash used in operations for the third quarter of 2015 was $71.7 million and $177.4 million for the first nine months of 2015, including $12.0 million in rociletinib milestone payments. In July 2015, the Company raised net proceeds of $298.5 million through an offering of 4.1 million shares of common stock.
>
> **2015 Key Milestones and Objectives**
>
> Highlights of planned or completed objectives for each product follows:
>
> Rociletinib
>
> Rociletinib is an investigational therapy for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation. The ***U.S. Food and Drug Administration (FDA) has accepted Clovis' New Drug Application (NDA) for rociletinib and has granted it priority review status with a Prescription Drug User Fee Act (PDUFA) action date of March 30, 2016. In addition, theEuropean Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for rociletinib.***
>
> The U.S. commercial and medical affairs organizations are now in place and efforts are currently underway to build out the E.U. commercial organization.
>
> ***Rociletinib was the subject of several posters and presentations during the third quarter, including updates of data from the TIGER-X study in EGFR mutant, T790M-positive patients with a history of CNS involvement, as well as EGFR mutant, T790M-negative patients as determined by tissue as well as plasma testing.*** Posters and presentations for all Clovis products in development presented during the third quarter may be viewed at http://clovisoncology.com/products-companion-diagnostics/scientific-presentations/.
>
> (Emphasis added).

50. On November 5, 2015, the Company held a conference call to discuss the earnings of the third quarter of 2015. On the call, Defendant Mahaffy emphasized the positive outlook and future plans for rociletinib, stating in relevant part:

> Our NDA and MAA submission for rociletinib for the treatment of advanced EGFR mutated T790M positive non-small cell lung cancer are on file with the US and EU regulatory authorities. ***We await FD action by March 30, 2016, based on our PDUFA date, and ENA action is expected in mid-2016***.
>
> ***As you'll hear, we are fully prepared for a launch now in the United States in the event that we receive an approval prior to our PDUFA date***. We raised $298 million in an equity offering in July and we're well capitalized as we prepare for the launch of rociletinib in the US and EU, potentially followed by rucaparib toward the end of next year.

* * *

Turning now to product updates, we will begin with rociletinib. ***As I mentioned, our regulatory filings for rociletinib in the US and Europe are under review. Based on priority review status granted by the FDA, we anticipate an action on or prior to March 30, 2016. We expect an action from the European authorities in mid-2016.***

Kiogen [ph] supplemental PMA filing for our companion diagnostic for Q7 IDM positive mutant EGFR non-small cell lung cancer is also under review in parallel with our NDA submissions.

As we are actively under review by both the ENA and FDA, we will be somewhat circumspect in our discussion of rociletinib today. We will say that our US commercial and medical affairs organizations are fully in place and preparing for potential launch of rociletinib.

We had an intense and exuberant launch meeting last week with our entire commercial organization, including about 100 new sales reps, and I am confident this great team is ready to go and well-prepared to launch rociletinib in the US upon a potential US approval. In addition, we are now in the process of building out our EU commercial organization in preparation for a potential late 2016 launch in the EU.

Turning briefly to rociletinib data presented during the third quarter, ***as many of you know, we provided updates of clinical data at both the World Conference on Lung Cancer and ESMO in September.***

These included a new set of data in T7IDM [ph] negative patients as well as in T7IDM positive patients with central nervous system involvement and a preclinical rationale for some of our combination studies. All of these presentations can be found on our website.

Turning now to rociletinib clinical development, we continue to enroll patients in the Phase 2 portion of TIGER-1, our randomized Phase 2/3 global registration study versus erlotinib in newly diagnosed patients. In TIGER-3, our randomized comparative study chemotherapy, in both T790M positive and T790M negative patients with acquired TKI resistance. TIGER-J, our Phase 2 study in Japanese patients, is expected to begin enrolling patients in Q1 2016.

(Emphasis added).

51. On the same conference call, Defendant Mast discussed rociletinib, stating in relevant part:

The increase in our net loss was primarily due to increased investment in research and development activities, ***and that includes rociletinib commercial launch***

> ***planning in 2015***, as well as the lack of a milestone revenue in 2015 as compared to 2014 when we did have some milestone revenue come in.
>
> Research and development expenses totaled $76.1 million for the third quarter of this year and $193.3 million for the first nine months of 2015. That compares to $35 million and $87.6 million in the comparable periods of 2014.
>
> These increases are due to expanded enrollment in the TIGER-X and the TIGER-2 studies for rociletinib. In the ARIEL2 and ARIEL3 studies for rucaparib, as well as the initiation of TIGER-1 and TIGER-3 and launch preparation activities for rociletinib and, of course, higher personnel costs to support all of those activities.
>
> Our general and administrative expenses were $8.3 million for the third quarter of this year and $22.3 million for the first nine months of 2015. And those amounts compare to $5.3 million and $15.9 million for 2014. These year-over-year increases are primarily due to higher share-based compensation expense and personnel costs, increased facility costs and higher professional service fees in 2015.
>
> We had acquired in-process research and development expenses totaling $12 million for both the third quarter and the first nine months of 2015. During this quarter, we made milestone payments to Celgene which totaled $12 million upon acceptance of the NDA and the MAA for rociletinib by each of the FDA and EMA respectively.
>
> Our net cash used in operations for the third quarter of 2015 was $71.7 million and $177.4 million for the first nine months of 2015 and each of those amounts include the $12 million in rociletinib milestone payments that I referred to just a minute ago.
>
> Now we continue to expect that our quarterly cash burn will increase in the fourth quarter of 2015, as again, enrollment in our clinical studies continue to grow and our launch preparation activities for rociletinib expand. We ended the third quarter with $605.9 million in cash and available for sale investments.
>
> (Emphasis added).

52. On November 6, 2015, the Company filed a Form 10-Q for the quarter ended September 30, 2015 (the "3Q 2015 10-Q") with the SEC, which provided the Company's quarterly financial results. The 3Q 2015 10-Q was signed by Defendants Mahaffy and Mast. The 3Q 2015 10-Q contained signed certifications pursuant SOX by Defendants Mahaffy and Mast, which stated that the financial information contained in the 3Q 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

53. The 3Q 2015 10-Q discussed the NDA for rociletinib, stating in relevant part:

> In July 2015, the Company submitted a New Drug Application ("NDA") regulatory filing and a Marketing Authorization Application ("MAA") for rociletinib to the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA"), respectively. Both the FDA and EMA subsequently accepted the respective filings for review. The FDA granted the rociletinib NDA priority review status with a Prescription Drug User Fee Act action date of March 30, 2016.
>
> * * *
>
> In May 2010, we entered into an exclusive worldwide license agreement with Avila Therapeutics, Inc. (now Celgene Avilomics Research, Inc., part of Celgene Corporation ("Celgene")) to discover, develop and commercialize a covalent inhibitor of mutant forms of the EGFR gene product. Rociletinib was identified as the lead inhibitor candidate under the license agreement. We are responsible for all preclinical, clinical, regulatory and other activities necessary to develop and commercialize rociletinib.
>
> We made an up-front payment of $2.0 million upon execution of the license agreement, a $4.0 million milestone payment in the first quarter of 2012 upon acceptance by the FDA of our Investigational New Drug application for rociletinib and a $5.0 million milestone payment in the first quarter of 2014 upon the initiation of the Phase II study for rociletinib. In the third quarter of 2015, we made milestone payments totaling $12.0 million upon acceptance of the NDA and MAA for rociletinib by the FDA and EMA, respectively. We recognized all payments as acquired in-process research and development expense.

54. The statements referenced in ¶¶ 16-53 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business and prospects for rociletinib, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the New Drug Application ("NDA") that Clovis submitted to the FDA for rociletinib contained immature data sets based on both unconfirmed response rates and confirmed response rates; (2) Clovis' Breakthrough Therapy designation submission contained immature data set based primarily on unconfirmed responses; (3) that Clovis presented interim data publicly and at medical meetings that included a data set based primarily on unconfirmed responses; (4) as the efficacy data matured, the number of patients with an unconfirmed response who converted to a confirmed response was lower than expected; (5) as a result of the foregoing, Clovis' NDA was likely to be delayed and/or rejected

by the FDA; and (6) Clovis was in possession of data during its third-quarter conference call held on November 5, 2015, which demonstrated that the confirmed rociletinib response rate is lowered than what was previously disclosed; and (7) as a result, Defendants' statements about the Company's business and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

THE TRUTH EMERGES

55. On November 16, 2015, the Company issued a press release entitled "Clovis Oncology Announces Regulatory Update for Rociletinib NDA Filing." The press release acknowledged that Clovis received additional bleak data for rociletinib that it submitted to the FDA but failed to publically reveal until now, stating in relevant part:

> CLOVIS ONCOLOGY ANNOUNCES REGULATORY UPDATE FOR ROCILETINIB NDA FILING
>
> - Mid-Cycle Communication Meeting with FDA completed
> - Additional clinical information for 500mg and 625mg BID dose groups to be provided by the Company today
>
> BOULDER, Colo.--(BUSINESS WIRE)--Nov. 16, 2015-- Clovis Oncology, Inc. (NASDAQ: CLVS) today announced that ***during its regularly scheduled Mid-Cycle Communication Meeting held last week with the U.S. Food and Drug Administration (FDA), the agency requested additional clinical data for use in the efficacy analysis for both the 500mg and 625mg BID dose patient groups for rociletinib.*** The Company will provide this information in a Major Amendment to the FDA by close of business today.
>
> "We remain confident in rociletinib and its potential to treat patients with mutant EGFR T790M-positive lung cancer, said Patrick J. Mahaffy, President and CEO of Clovis Oncology. "We will continue to work diligently with the FDA on our NDA submission."
>
> ***In the Mid-Cycle Communication meeting, the FDA emphasized that its efficacy analysis would focus solely on confirmed responses. The New Drug Application (NDA) submitted by Clovis to the FDA contained immature data sets based on both unconfirmed response rates and confirmed response rates. These data sets were updated in the 90 day efficacy update the Company submitted at the end of October.***
>
> As the rociletinib clinical trials were rapidly enrolling, C***lovis presented interim data publicly and at medical meetings and these data therefore included a data set based primarily on unconfirmed responses. This was also true of the Company's Breakthrough Therapy designation submission. In the Company's NDA submission, both immature confirmed and unconfirmed response analyses were submitted. As the efficacy data have matured, the number of***

> ***patients with an unconfirmed response who converted to a confirmed response was lower than expected.***
>
> In the intent to treat analysis of the 79 patients in the 500mg dose group, the current confirmed response rate is 28 percent, and 34 percent in the 170 patients in the 625mg dose group, with an encouraging duration of response in both doses. The most frequent reasons that patients' responses were not confirmed in a subsequent scan were due to progression, often due to brain metastasis, and due to subsequent scans not demonstrating tumor shrinkage greater than 30 percent.
>
> The Company anticipates that the review of this additional information will result in a delay of a potential approval. This additional review could lead to an extension of the Company's March 30, 2016 Prescription Drug User Fee Act (PDUFA) date.
>
> * * *
>
> About Rociletinib
>
> Rociletinib is the company's novel, oral, targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M. Data from both the pivotal, single-arm TIGER-X and TIGER-2 clinical trials served as the basis for the U.S. and EU regulatory submissions for the treatment of advanced mutant EGFR T790M-positive lung cancer. Rociletinib was given Breakthrough Therapy designation by the FDA in May 2014.
>
> (Emphasis added).

56. The same day, Clovis held a conference call to discuss the regulatory update. On the conference call, Defendant Mahaffy stated in relevant part:

- In the mid-cycle communication meeting, the FDA emphasized that its efficacy analysis would focus solely on confirmed responses. The NDA submission contained immature data sets based on both unconfirmed response rates and confirmed response rates. ***These data sets were updated in the 90-day efficacy update we submitted to the FDA at the end of October.***

- ***As rociletinib clinical trials were rapidly enrolling, we presented interim data publicly and at medical meetings and these data therefore included a data set based primarily on unconfirmed responses. This was also true of our breakthrough therapy destination submission and our NDA submission; both immature confirmed and unconfirmed response analyses were submitted***.

- ***As the efficacy data had matured, the number of patients with an unconfirmed response who converted to a confirmed response was lower than expected***. In the intent-to-treat analysis of the 79 patients in the 500 milligrams dose group, the current confirmed response rate is 28% and in the 170 patients in the 625 milligram dose group, it's 34%. In both cases we have a duration of response of nine months.

(Emphasis added).

57. Additionally on this conference call, Defendant Mahaffy engaged in the following interaction with Bob Ai, an analyst at Wallach Beth Capital:

Bob Ai - *Wallach Beth Capital - Analyst*

So I may also have missed the beginning of the call a little bit. ***I remember you are talking about this data were available at the end of October, am I right?***

Patrick Mahaffy - *Clovis Oncology, Inc. - President, CEO & Director*

We did a 90-day update that we provided at the end of October. That is when we provide the update. We had no communication related to that update from FDA until last week.

Bob Ai - *Wallach Beth Capital - Analyst*

Okay, ***so when you did the 3Q conference call, at that time — was that data available at that time of the conference call?***

Patrick Mahaffy - *Clovis Oncology, Inc. - President, CEO & Director*

No. ***Well, we had data***. We didn't have an FDA interaction related to those data.

(Emphasis added).

58. On this news, the Company's shares plummeted $69.19 per share or approximately 70% from its previous closing price to close at $30.24 per share on November 16, 2015, damaging investors.

59. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

60. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Clovis securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

61. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Clovis securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Clovis or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

62. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

63. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

64. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Clovis;
- whether the Individual Defendants caused Clovis to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Clovis securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

65. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

66. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Clovis securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Clovis securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

67. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

68. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material

information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

NO SAFE HARBOR

69. Clovis' "Safe Harbor" warnings accompanying its reportedly forward looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with GAAP, they are excluded from the protection of the statutory Safe Harbor. See 15 U.S.C. §78u-5(b)(2)(A).

70. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Clovis who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

COUNT I

VIOLATIONS OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10B-5 AGAINST ALL DEFENDANTS

71. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

72. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

73. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state

material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Clovis securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Clovis securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

74. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Clovis securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Clovis' disclosure controls and procedures.

75. By virtue of their positions at Clovis, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

76. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Clovis, the Individual Defendants had knowledge of the details of Clovis' internal affairs.

77. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Clovis. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Clovis' businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Clovis securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Clovis' business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Clovis securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

78. During the Class Period, Clovis securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Clovis securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Clovis securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Clovis securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

79. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

80. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure

that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

VIOLATIONS OF SECTION 20(A) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

81. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

82. During the Class Period, the Individual Defendants participated in the operation and management of Clovis, and conducted and participated, directly and indirectly, in the conduct of Clovis' business affairs. Because of their senior positions, they knew the adverse non-public information about Clovis' operations, current financial position and future business prospects.

83. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Clovis' business practices, and to correct promptly any public statements issued by Clovis which had become materially false or misleading.

84. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Clovis disseminated in the marketplace during the Class Period concerning the Company's disclosure controls and procedures. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Clovis to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Clovis within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Clovis securities.

85. Each of the Individual Defendants, therefore, acted as a controlling person of Clovis. By reason of their senior management positions and/or being directors of Clovis, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Clovis to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Clovis and possessed the power to

control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

86. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Clovis.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as her reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: November 20, 2015

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

/s/ Laurence M. Rosen

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